2021-1154

United States Court of Appeals for the Federal Circuit

CELGENE CORPORATION,

Plaintiff-Appellant,

– v. –

MYLAN PHARMACEUTICALS INC., MYLAN INC., MYLAN N.V.,

Defendants-Appellees.

On Appeal from the United States District Court for the District of New Jersey in No. 2:19-cv-05802-ES-MAH Honorable Esther Salas, Judge

NON-CONFIDENTIAL BRIEF FOR PLAINTIFF-APPELLANT

MATTHEW J. HERTKO
JONES DAY
Suite 3500
77 West Wacker Drive, Suite 3500
Chicago, Illinois 60601
(312) 782-3939
mhertko@jonesday.com

– and –

JENNIFER L. SWIZE
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001
(202) 879-3939
jswize@jonesday.com

F. DOMINIC CERRITO
ERIC C. STOPS
ELLYDE R. THOMPSON
FRANK C. CALVOSA
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000
nickcerrito@quinnemanuel.com
ericstops@quinnemanuel.com
ellydethompson@quinnemanuel.com
frankcalvosa@quinnemanuel.com

Attorneys for Plaintiff-Appellant

JANUARY 19, 2021

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2021-1154

Short Case Caption Celgene Corporation v. Mylan Pharmaceuticals Inc.

Filing Party/Entity Celgene Corporation

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box**. Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

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Name: F. Dominic Cerrito

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
Celgene Corporation		Bristol Myers Squibb

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☑ Additional pages attached

SEE ATTACHED		

5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

☐ None/Not Applicable ☐ Additional pages attached

Celgene Corporation v. Hetero Labs Limited, et al., No. 17-cv-3387 (D.N.J.)		

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

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Quinn Emanuel Urquhart & Sullivan, LLP
Evangeline Shih
Andrew S. Chalson
Gabriel P. Brier
Marta A. Godecki
Brian J. Forsatz, Ph.D.

Jones Day
Anthony M. Insogna
Cary Miller, Ph.D.

Saul Ewing Arnstein & Lehr LLP
Charles M. Lizza
William C. Baton
Sarah A. Sullivan

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CONFIDENTIAL MATERIAL OMITTED

The material redacted from this brief is subject to a protective order governing confidential information pertaining to venue discovery. The underlying material details the physical presence of Defendants-Appellees Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan N.V. in New Jersey. The redacted material on pages 3-4, 9-15, 17, 21, 31-44, and 46-47 has been designated either "Venue Discovery Highly Confidential Information," "Outside Attorneys' Eyes-Only Venue Information," or "Highly Confidential" by Defendants-Appellees Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan N.V.

TABLE OF AUTHORITIES

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STATEMENT OF RELATED CASES

No related appeal has been decided by or is currently pending before this Court. *Celgene Corp. v. Hetero Labs Ltd., et al.*, No. 17-cv-3387 (D.N.J), is pending in the U.S. District Court for the District of New Jersey. In that case, through an order that was applied by stipulation of the parties to the action underlying the instant appeal, the district court dismissed defendants Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan, N.V. That action continues against the other defendants in that case and no final judgment has been entered.

INTRODUCTION

This is an appeal from the U.S. District Court for the District of New Jersey (Hammer, M.J.) in a patent infringement action stemming from an Abbreviated New Drug Application ("ANDA") filed with the U.S. Food and Drug Administration ("FDA") to sell a generic version of the cancer treatment drug Pomalyst®. Appellant Celgene Corporation ("Celgene") developed, markets, and sells Pomalyst®, a drug in the form of pomalidomide capsules used to treat multiple myeloma, and holds numerous patents for the drug. The Appellees here—defendants Mylan Pharmaceutical Inc. ("MPI"), Mylan Inc., and Mylan N.V.—regularly develop, market, and sell generic versions of brand-name drugs. In 2017, the Mylan defendants submitted an ANDA for a generic version of Pomalyst®.

Following venue-related discovery, the district court dismissed foreign entity Mylan N.V. for failure to state a claim pursuant to 35 U.S.C. § 271(e)(2) and dismissed MPI and Mylan Inc. for improper venue. In analyzing the adequacy of the Complaint under Federal Rule of Civil Procedure 12(b)(6) as to Mylan N.V.—a foreign entity as to which venue was admittedly proper—the district court held that documents contradicted Celgene's allegations that Mylan N.V. submitted the ANDA, and it disregarded allegations that Mylan N.V. would benefit from the approval of the ANDA. In analyzing venue as to MPI and Mylan Inc. under the patent venue statute, 28 U.S.C. §1400(b), the district court concluded that each

entity lacked a regular and established place of business in the district. These holdings were in error.

As to the dismissal of Mylan N.V., the district court applied an erroneous and unduly restrictive definition of the term "submit" in the context of an ANDA filing. *See* 35 U.S.C. § 271(e)(2) ("It shall be an act of infringement to submit . . . an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent."). This Court has recognized that a submitter may encompass more than the entity listed on the ANDA filing itself. Celgene alleged sufficient facts as to Mylan N.V.'s coordination with the other Mylan entities to develop, market, and sell generic drugs and as to Mylan N.V.'s future involvement if the ANDA is approved. Celgene—which could not have known when it filed its Complaint (prior to discovery) exactly which entities took what actions in relation to the ANDA—alleged that each of the three Mylan defendants prepared the ANDA filing and would benefit from its approval. The district court thus erred in holding that the fact that MPI was the sole named ANDA applicant foreclosed any possible claim against Mylan N.V. At a minimum, the district court abused its discretion in denying Celgene leave to amend to add allegations regarding Mylan N.V.'s role in preparing and submitting the ANDA.

As to the dismissal of MPI and Mylan Inc. for improper venue, the district court erred in concluding that MPI and Mylan Inc. did not have regular and established places of business in the district. *See* 28 U.S.C. § 1400(b) ("Any civil action for patent infringement may be brought . . . where the defendant has committed acts of infringement and has a regular and established place of business."). MPI has more than a [redacted] employees in the district. As part of their employment, MPI employees must rent a physical space in the district to [redacted]. And [redacted] employees list their [redacted] in the district on their [redacted]. Likewise, Mylan Inc. has [redacted] employees in the district who have established [redacted] from which they carry out essential functions for Mylan Inc. MPI and Mylan Inc. each have both a stable physical presence and agents in the district, which is sufficient under this Court's precedent. The district court's evaluation of the relevant venue facts was erroneous and contravenes this Court's guidance. And, in any event, venue may be imputed to both MPI and Mylan Inc. based on the Mylan affiliates in the district, and venue is proper under the general venue statute, 28 U.S.C. § 1391, to the extent it applies to forward-looking ANDA infringement actions just as it applies to declaratory judgment actions.

The judgment of the district court should be reversed.

STATEMENT OF JURISDICTION

The district court had jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). It entered final judgment on September 25, 2020. Celgene timely filed a notice of appeal on October 23, 2020. This Court has jurisdiction under 28 U.S.C. § 1295(a).

STATEMENT OF ISSUES

1. Whether the district court erred in dismissing Mylan N.V. for failure to state a claim for patent infringement under 35 U.S.C. § 271(e)(2) or abused its discretion in failing to grant leave to amend—on the basis that Mylan N.V. was not listed as the ANDA applicant or the sender of Mylan's written certification for that ANDA.

2. Whether the district court erred in dismissing MPI and Mylan Inc. for improper venue based on its conclusion that MPI and Mylan Inc. lack a regular and established place of business in the district even though both entities have long-term employees in the district, MPI requires its employees to venue discovery Mylan venue discovery in the district, employees list their confidential venue discovery on their venue discovery, the employees' actions resulted in venue discovery of venue discovery of dollars of sales in the district, MPI and Mylan Inc. are presented to the public as part of "One Mylan" with other affiliates having a physical presence in New Jersey, and venue would be proper under 28 U.S.C. § 1391.

STATEMENT OF THE CASE

A. Mylan's Application For Approval To Market A Generic Version Of Celgene's Pomalyst® Drug Product Throughout The United States

This is a Hatch-Waxman action arising out of the Mylan defendants' submission of an ANDA to the FDA, seeking approval to market generic versions of Celgene's Pomalyst® drug products (the "Proposed Products"), before certain of Celgene's patents covering Pomalyst® expire. Celgene holds approved New Drug Application ("NDA") No. 204026 under Section 505(a) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 355(a), for pomalidomide capsules, which it sells under the trade name Pomalyst®. Appx117. Pomalyst® is an FDA-approved medication used for the treatment of multiple myeloma. Appx117. Celgene holds numerous patents covering the methods of use and administration of pomalidomide, pharmaceutical compositions composing pomalidomide, and solid forms (or polymorphs) of pomalidomide.[1]

In February 2017, the Mylan defendants submitted ANDA No. 210275 to the FDA, seeking approval to commercially market generic versions of Celgene's 1 mg, 2 mg, 3 mg, and 4 mg Pomalyst® drug products prior to the expiration of

[1] United States Patent Nos. 8,198,262 (the "'262 patent"); 8,673,939 (the "'939 patent"); 8,735,428 (the "'428 patent"); 8,828,427 (the "'427 patent"); 9,993,467 (the "'467 patent"); 10,093,647 (the "'647 patent"), Appx133-153; 10,093,648 (the "'648 patent"), Appx144-173; 10,093,649 (the "'649 patent"), Appx174-192; and 10,555,939 (the "'5,939 patent").

certain of Celgene's patents. Appx115-116, Appx2322-2327. Mylan's ANDA contained written certifications to the FDA made pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification")[2], alleging, *inter alia*, that the claims of the '262, '939, '428, and '427 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Mylan's ANDA. Appx120. On April 6, 2017, Mylan sent written notice of its ANDA to Celgene in New Jersey. Appx122, Appx1808. This notice alleged, *inter alia*, that the claims of the '262, '939, '428, and '427 patents are invalid and/or will not be infringed by the activities described in Mylan's ANDA. Appx122.

Celgene filed several actions in the District of New Jersey alleging that ANDA submissions for approval to market and sell generic versions of Pomalyst® infringed its patents. Celgene filed its first action in New Jersey on May 11, 2017, asserting claims for patent infringement against the Mylan defendants and other manufacturers that had similarly submitted ANDAs seeking to market generic versions of Celgene's Pomalyst® drug products, captioned *Celgene Corp. v. Hetero Labs Ltd., et al.*, No. 17-cv-3387 (D.N.J.). Appx40.

[2] A Paragraph IV certification states that a patent associated with the drug for which the applicant seeks approval to market a generic version is "invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

After Celgene filed those actions, the U.S. Patent and Trademark Office ("PTO") issued to Celgene the '467 patent, the '647 patent, the '648 patent, the '649 patent, and the '5,939 patent. Appx41; *see* n.1, *supra*. On September 28, 2018, Mylan sent a second written notice of its ANDA to Celgene in New Jersey. Appx122-123. The second notice alleged that the claims of the '467 patent are invalid and/or will not be infringed by the activities described in Mylan's ANDA. Appx122. Mylan's second notice also informed Celgene that Mylan seeks approval to market the Proposed Products before the '467 patent expires. Appx122-123. On November 9, 2018, Celgene filed in New Jersey a patent infringement action relating to the '467 patent. *See Celgene Corp. v. Mylan Pharms. Inc., et al.*, No. 18-cv-16035, Doc. 1 (D.N.J. Nov. 9, 2018). The district court consolidated Celgene's action pertaining to the '467 patent with Celgene's action in No. 17-cv-3387 pertaining to the '262, '939, '428, and '427 patents (together, the "Consolidated Actions"). Appx41.

This appeal concerns a third-filed action, related to Celgene's '647, '648, and '649 patents, all of which cover solid forms (or polymorphs) of pomalidomide. Appx117. Specifically, on November 20, 2018, Celgene sent a written notice to counsel for Mylan informing Mylan that its Proposed Products will likely infringe one or more claims of the '647 patent, the '648 patent, and the '649 patent. Appx123. Celgene requested that, should Mylan disagree with Celgene's

infringement allegations, Mylan produce samples of its Proposed Products, the active pharmaceutical ingredient used to make the Proposed Products, and additional documentation concerning the representativeness of the requested samples, as well as all safety, storage, and handling information that Mylan deems appropriate for its samples. Appx123. Mylan did not respond to Celgene's letter. Appx123.

Accordingly, on February 14, 2019, Celgene filed a complaint against Mylan N.V., MPI, and Mylan Inc. alleging infringement of the '647 patent, the '648 patent, and the '649 patent in *Celgene Corp. v. Mylan Pharmaceuticals, et al.*, No. 19-cv-5802, Doc. 1 (D.N.J. Feb. 14, 2019), the action underlying this appeal. The Complaint contains numerous allegations regarding the Mylan defendants' coordination, including that: Mylan Inc. is an indirect wholly-owned subsidiary of Mylan N.V., Appx120; MPI, Mylan Inc., and Mylan N.V. work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, Appx120; MPI acts at the direction, and for the benefit, of Mylan N.V. and Mylan Inc., and is controlled and dominated by Mylan N.V. and Mylan Inc., Appx120; and Mylan Inc. and MPI prepare and/or aid in the preparation and submission of ANDAs to the FDA, Appx118-119. That action was not consolidated with the earlier filed actions concerning Celgene's Pomalyst® drug products.

At the time Celgene filed the action underlying this appeal, the district court had denied without prejudice the Mylan defendants' motion to dismiss for improper venue and failure to state a claim in the Consolidated Actions, directing the parties to conduct venue-related discovery. *See Celgene Corp. v. Hetero Labs Ltd.*, 2018 WL 1135334 (D.N.J. Mar. 2, 2018). Celgene and the Mylan defendants thereafter stipulated that the final resolution of Mylan's renewed motion to dismiss for improper venue and failure to state a claim in the Consolidated Actions after the completion of venue discovery would apply equally in the action underlying this appeal. Appx221.

B. Mylan's Regular And Established New Jersey Operations

Venue discovery revealed that both MPI and Mylan Inc. have a regular and established place of business in New Jersey.

To start, the Mylan entities conduct business through confidential venue discovery MPI and venue discovery Mylan Inc.) employees who reside in that district. Appx2537. A number of these employees worked in New Jersey for the Mylan entities for years before this action began, Appx2537, Appx2539-2542, Appx2544-2545, and provided confidential venue discovery and/or confidential venue discovery as their work contact information, Appx2681-2683. venue discovery in the record for venue discovery of these employees show the venue discovery company name and logo on the front with the

confidential venue discovery, and list a venue discovery street venue discovery. Appx2681-2683.

Mylan Inc. employs venue discovery individuals who live and conduct their business in New Jersey, serving confidential venue discovery, and confidential venue discovery functions. Appx2537. For its part, MPI employs venue discovery individuals who each live and work in New Jersey—venue discovery and venue discovery employees and a "confidential venue discovery." Appx2537. The confidential venue discovery operating out of New Jersey play an important role in MPI's business, with more than venue discovery in sales of tangible personal property shipped to locations in New Jersey for 2016. Appx2550-2551, Appx2553. When Mylan entities post a job opportunity regarding sales and marketing, the job postings often identify specific locations and require individuals to "live within [the] territory," Appx2553, or "live within [the] geography or within reasonable driving distance," Appx2547, Appx2551. The location of its venue discovery and venue discovery employees—including those in New Jersey—is vital for Mylan to "achieve quarterly sales goals within the territory." Appx2547, Appx2550.

Certain of the MPI employees conducting business out of venue discovery accessed confidential venue discovery that were venue discovery in venue discovery in New Jersey. Appx2537, Appx2667-2674, Appx2676-2679, Appx2719-2720. MPI employees venue discovery the venue discovery for business purposes and venue discovery MPI employees used

the same venue discovery. *Compare* Appx2676-2679 (confidential venue discovery agreement listing venue discovery as a customer, and allowing venue discovery to access the venue discovery) *with* Appx2537 (a venue discovery of Mylan employees based in venue discovery including venue discovery venue discovery and venue discovery). As part of their employment as venue discovery and venue discovery venue discovery, employees had access to and were required to access the venue discovery venue discovery there. Appx2537, Appx2667-2674, Appx2676-2679, Appx2719-2720.

Mylan entities emphasize their intertwined relationship, encompassing Mylan employees who operate out of New Jersey, as part of Mylan's prominent "One Mylan" campaign touting a "horizontally and vertically integrated platform with global scale." Appx327. Mylan represents to the outside world that its entities comprise one unified company and, when Mylan's New Jersey subsidiary Dey Pharma changed its name to "Mylan Specialty" in 2012, Mylan's CEO stated that "operating under one brand will allow us to speak with a more unified and powerful voice." Appx525. As part of "One Mylan," the employees of Mylan who reside in New Jersey all use one "@mylan.com" email domain address, and Mylan uses one website in the United States with one hiring webpage, one newsroom for press releases (including those involving subsidiaries), and the same customer-service email address for products from all Mylan entities, *see* Appx549, Appx553 (showing that Mylan uses customer.service@mylan.com for new drug

applications made by other Mylan entities). Notably, one of the employees of Mylan Inc. who worked on the ANDA at issue in this action did not even know which Mylan entity employed him. Appx2695.

In addition, the Mylan entities are closely intertwined in their interactions with regulatory authorities and regarding intellectual property. For example, in correspondence with the FDA signed by an individual from MPI, Mylan grouped its affiliated corporate entities together, requesting "that the 'affiliated' corporate entities . . . be consolidated under 'Mylan Inc.' for purposes of assessing a single [Generic Drug User Fee Amendments] II program fee." Appx774-775. Another letter to the FDA was sent by MPI, on behalf of Mylan Inc., and signed by an individual at Mylan N.V. *See* Appx721-725. And when petitions for *inter partes* review are brought by Mylan before the PTO, MPI describes Mylan Inc. and Mylan N.V. as the "real parties in interest." Appx2740. *See Applications in Internet Time, LLC v. RPX Corp.*, 897 F.3d 1336, 1348 (Fed. Cir. 2018) ("[T]he real-party-in-interest inquiry … bear[s] in mind who will benefit from having those claims cancelled or invalidated."). The ANDA for the generic version of Pomalyst®, which lists MPI as the ANDA applicant, includes several references to venue discovery including for information considered to be the "venue discovery confidential venue discovery of venue discovery" Appx1068-1071; *see also* Appx1066

(confidential venue discovery addressed to venue discovery); Appx1077 (naming venue discovery as "Name of venue discovery).

C. The District Court's Opinion

In April 2020, following the close of venue-related discovery in the Consolidated Actions, the Mylan defendants renewed their motion to dismiss, seeking dismissal for improper venue and dismissal of the claims against Mylan Inc. and Mylan, N.V. for failure to state a claim. Appx45. The district court in the Consolidated Actions granted Mylan's motion to dismiss on September 2, 2020. Appx39-40. As noted above, the parties in the instant case agreed that the resolution of Mylan's renewed motion in the Consolidated Actions would control here, and the district court dismissed the Complaint on September 25, 2020. Appx221. Accordingly, the following summary, while arising in the context of the Consolidated Actions, applies here.[3]

The district court dismissed Mylan, N.V. under Rule 12(b)(6) after discarding certain allegations based on the ANDA filing and Paragraph IV certification, which listed only MPI. Appx76-81. The district court denied leave

[3] The parties in the Consolidated Actions consented to the Magistrate Judge's jurisdiction concerning the renewed motion to dismiss, including plenary authority to enter a final order on that motion. *See Celgene Corp. v. Hetero Labs Ltd., et al.*, No. 17-cv-3387, Doc. 710 (D.N.J. May 14, 2020).

to amend based on the length of time the Consolidated Actions had been pending. Appx81.

The district court also dismissed MPI and Mylan Inc. for improper venue, holding that neither MPI nor Mylan Inc. had a regular and established place of business in the district under Section 1400(b). After concluding that neither Mylan Inc. nor MPI possesses a "fixed, physical presence in New Jersey," the district court assessed whether venue was proper based either on the entities' employees living and working in New Jersey, Appx56-62, or the entities' relationship with affiliated Mylan companies, including Mylan Laboratories Inc. ("MLI"), Appx62-75. With regard to Mylan Inc.'s venue discovery employees, the district court denied the sufficiency of evidence showing that they lived and worked in New Jersey. Appx56-58. As to MPI's venue discovery employees, including those with access to venue discovery venue discovery and accessed in the district, and the Mylan job posting for a sales position in New Jersey, the district court concluded that Celgene failed to adduce evidence sufficient to indicate that MPI ratified its employees working from their residences in New Jersey. Appx60-62.

With regard to the entities' relationship with affiliated Mylan companies that did indisputably operate out of New Jersey, the district court declined to impute venue to MPI or Mylan Inc. Appx76. The district court rejected Celgene's argument that the existence of affiliates in a forum supported venue proper in that

forum, and held that venue would be proper only if Mylan "disregarded the corporate form in their dealings with their respective subsidiaries and affiliates." Appx66. The district court concluded that the Mylan entities had not so disregarded the corporate form in its dealings with MLI. Even though MLI's venue discovery venue discovery was also an venue discovery of venue discovery, the termination of MLI's lease was effectuated by an venue discovery of venue discovery, and MLI portrayed itself as doing business as MPI in government records, the district court declined to conclude that MLI's finances, policies, and business practices were "completely dominated" by another Mylan entity. Appx70-72. The district court also held that Celgene failed to show "that adherence to the fiction of separate corporate existence would sanction a fraud or promote injustice," rejecting Celgene's argument that venue based on Mylan affiliates in the district would prevent forum shopping or effectuate the purposes of the Hatch-Waxman Act. Appx75-76.

SUMMARY OF ARGUMENT

I

The district court's dismissal of Mylan N.V. for failure to state a claim misapplies the relevant law and ignores the relevant factual allegations. The district court's primary rationale for holding that Celgene had not stated a claim for patent infringement against Mylan N.V. in connection with the ANDA submission rests on the notion that Mylan N.V. cannot qualify as a "submitter" of the ANDA

because MPI was the sole named applicant for the ANDA with the FDA. But this Court has held that the "submitter" of an ANDA extends beyond the named applicant to those entities involved in the preparation of the ANDA and those entities that will benefit from sales of the generic product if the ANDA is approved. The Complaint pleads such facts as to Mylan N.V., and thus application of the correct law requires reversal.

At a minimum, the district court abused its discretion in denying Celgene's request for leave to amend. The district court's reasoning—that the time for amendment had passed and that the Mylan defendants previously had moved to dismiss, thus putting Celgene on notice—fails to account for the fact that the court had *denied* the Mylan defendants' prior motion to dismiss and that other courts have held patent infringement claims adequately pleaded based on similar allegations to those that Celgene included in its original Complaint (thus, leaving Celgene to believe there were no inadequacies). The district court's rejection of Celgene's request for leave to amend as inconsistent with the scheduling order for the Consolidated Actions contravenes the well-established policy of liberally permitting amendment and, in any event, has no relevance to the Complaint at issue in this appeal. Celgene requested as alternative relief the ability to amend the Complaint on May 29, 2020, before the July 31, 2020 deadline for amendment of the Complaint in the action underlying this appeal.

II

The district court's dismissal of Mylan Inc. and MPI based on improper venue likewise should be reversed because each of the factors this Court set forth in *In re Cray*, 871 F.3d 1355 (Fed. Cir. 2017), for establishing that a defendant has a "regular and established place of business" under Section 1400(b) in the district, is met here. MPI alone has more than a [redacted] employees in the district. Mylan products are [redacted] in a [redacted] space in the district and accessed by multiple MPI employees. [redacted] MPI employees list their [redacted] on their Mylan [redacted], holding their homes out to the public as the place of business of the Mylan entity. And Mylan Inc. has [redacted] employees in the district who have established [redacted] from which they carry out essential functions for Mylan Inc. MPI and Mylan Inc. each have both a stable physical presence and agents in the district, which is sufficient under this Court's precedent for demonstrating that a defendant has a "regular and established place of business" in the district.

But even if those connections were insufficient, the district court erred in failing to impute venue to both MPI and Mylan Inc. based on the Mylan affiliates in the district. Mylan operates as one company, and presents itself to the public as such, meaning that the places of business of affiliates in New Jersey may also be considered those of MPI and Mylan Inc. Also, the interrelatedness of Mylan

N.V.'s subsidiaries and affiliates and their operations supports imputation of venue between Mylan entities. And venue is proper under the general venue statute because it applies to forward-looking ANDA infringement actions just as it applies declaratory judgment actions.

This Court's recent decision in *Valeant Pharmaceuticals North America LLC v. Mylan Pharmaceuticals Inc.*, 978 F.3d 1374 (Fed. Cir. 2020), *pet. for reh'rg en banc pending*, No. 19-2402, Doc. 75 (Fed. Cir. Dec. 7, 2020), does not foreclose a holding that venue is proper in New Jersey. The district court correctly held that the Mylan defendants had committed acts of infringement in New Jersey based on this Court's case law establishing that the "highly artificial act of infringement" associated with ANDA filings occurs nationwide. Even setting aside the scope of the ANDA submission, an interpretation of Section 1400(b) to provide for venue where the effects of infringement are felt accords with the interpretation of other venue statutes with similar language. And, while the Court in *Valeant* held venue is "proper only in those districts that are sufficiently related to the ANDA submission," the ANDA submission requires a Paragraph IV certification, which in turn requires proof that the filer notified the patent holder of the assertion in the ANDA that the patents are invalid or will not be infringed. Here, MPI sent that notice to Celgene in New Jersey. That notice is part of Mylan's ANDA submission and gave rise to the litigation. It, thus, is

unquestionably "sufficiently related to the ANDA submission" and satisfies the test set forth in *Valeant*.

ARGUMENT

I. THE DISTRICT COURT ERRED IN DISMISSING THE CONTROLLING PARENT, MYLAN N.V.

The district court erred in dismissing Mylan N.V. based upon its misapplication of the law defining who constitutes a "submitter" of an ANDA and disregarding facts pleading that Mylan N.V. will benefit from the ANDA, if approved. At a minimum, the district court abused its discretion in denying leave to amend the Complaint against Mylan N.V., in contravention of Third Circuit law providing for the denial of leave to amend only in narrow circumstances not present here.

A. Standard Of Review

This Court "appl[ies] regional circuit law when reviewing motions to dismiss for failure to state a claim." *Visual Memory LLC v. NVIDIA Corp.*, 867 F.3d 1253, 1257 (Fed. Cir. 2017). The Third Circuit "review[s] de novo a district court's grant of a motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6)." *Id.* (quoting *Ballentine v. United States*, 486 F.3d 806, 808 (3d Cir. 2007)). Regional circuit law also governs this Court's review of a district court's denial of leave to amend. *See Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1363 (Fed. Cir. 2017). The Third Circuit

"review[s] the denial of a motion for leave to amend for abuse of discretion." *Menkes v. Prudential Ins. Co. of Am.*, 762 F.3d 285, 290 (3d Cir. 2014). But that "discretion, circumscribed by Rule 15's directive in favor of amendment, must be exercised within the context of liberal pleading rules." *Mullin v. Balicki*, 875 F.3d 140, 150 (3d Cir. 2017) (citations and quotations omitted).

B. The District Court Erred In Holding That Celgene Failed To State A Claim Against Mylan N.V.

Federal Rule of Civil Procedure 8(a)(2) "generally requires only a plausible 'short and plain' statement of the plaintiff's claim." *Skinner v. Switzer*, 562 U.S. 521, 530 (2011); *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "The touchstone of the pleading standard is plausibility." *Bistrian v. Levi*, 696 F.3d 352, 365 (3d Cir. 2012). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw a reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citation omitted). Factual allegations in the Complaint must be taken as true in assessing whether a Complaint states a claim for relief. *See Twombly*, 550 U.S. at 556.

The district court erred in dismissing Mylan N.V. because the Complaint plausibly pleads a patent infringement claim against Mylan N.V.

First, the district court erred in declining to "credit Celgene's allegations that Mylan, N.V. submitted the ANDA that serves as the basis for the infringement

claims at issue," reasoning that "[a]s the documents themselves bear out, venue discover confidential venue discovery ANDA No. 210275, and sent the notice of certification letter to Celgene in regard to … venue discovery proposed pomalidomide product." Appx80. As a result, the district court concluded that "Celgene's allegations that Mylan N.V. submitted the relevant documents are therefore belied by the content of those documents." Appx80. But this Court has rejected the idea—including mere months ago in a case involving Mylan entities—that only the signatories of ANDA filings are considered "submitters." *See Valeant*, 978 F.3d at 1384 ("Whether MLL can be held answerable to claims of infringement in this case turns on whether MLL's involvement in the submission of the ANDA is sufficient for it to be considered a 'submitter,' and thus, amenable to suit.") (citing *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 527-29 (Fed. Cir. 2012)). Courts routinely define a "submitter" to include any party that intends to benefit from the ANDA if approved. *See, e.g.*, *Rosuvastatin*, 703 F.3d at 527-29; *Helsinn Healthcare S.A. v. Hospira, Inc.*, 2016 WL 1338601, at *7 (D.N.J. Apr. 5, 2016) ("§ 271(e)(2) does not explicitly require [an entity] to sign the ANDA in order for it to be a properly-named defendant.").

Indeed, in *Valeant*, the Court addressed a similar situation to that present here because the complaint in *Valeant* defined "Mylan" to include all Mylan defendants, and alleged that "Mylan" submitted the ANDA. *Valeant*, 978 F.3d at

1385 ("[E]ight other paragraphs in the complaint asserting that 'Mylan'—defined to encompass all three entities—'submitted' the ANDA and materials related to it."). This Court remanded the case even though the complaint also "asserted that only MPI was involved in submitting the ANDA." *Id.* Under these facts, this Court held that, on remand, the district court in that case "may well find that these paragraphs are sufficient to state a claim against MLL" or grant leave to amend "to clarify any apparent confusion." *Id.* The district court's unduly restrictive interpretation of "submit" in the context of ANDA filings here thus is contrary to this Court's precedent, and the district court erred in disregarding allegations that Mylan N.V. "submitted" the ANDA.

Second, the district court wrongly "discard[ed]" allegations that "[MPI] acts at the direction, and for the benefit of, Mylan N.V. and Mylan Inc., and is controlled and/or dominated by Mylan N.V. and Mylan Inc." Appx79. The district court held that such allegations were "conclusory" but did so based on the requirements necessary to pierce the corporate veil. Appx79 (reasoning that plaintiff must allege "specific facts … *in order to rely on an alter ego theory*" (emphasis added) (citing *High 5 Games, LLC v. Marks*, 2019 WL 3761114, at *6, 12 (D.N.J. Aug. 9, 2019)). But Celgene was not required to plead facts sufficient to pierce the corporate veil to show that Mylan N.V. had a hand in the submission of the ANDA or that it would benefit from approval. *See, e.g.*, *Valeant*, 978 F.3d

at 1385; *Warner Chilcott Co. v. Mylan Pharms.*, 2017 WL 603309, at *4 (E.D. Tex. Jan. 19, 2017), *report and recommendation adopted*, 2017 WL 590295 (E.D. Tex. Feb. 14, 2017) (recommending plaintiff stated a claim that each Mylan entity "submitted" the ANDA under § 271(e)(2) based on allegations that Mylan entities are "agents of each other" that "work in active concert either directly or through one or more of their wholly owned subsidiaries"); *Allergan, Inc. v. Teva Pharm. USA, Inc.*, 2016 WL 1572193, at *5 (E.D. Tex. Apr. 19, 2016) (Bryson, Circuit Judge) (similar).

As this Court made clear in *Rosuvastatin*, liability for patent infringement in a Hatch-Waxman action extends to an entity's "agent and subsidiary." 703 F.3d at 529; *see also id.* at 530 (Plager, J., concurring) ("[I]it is the real party in interest—the commercial manufacturer—who is the statutory applicant who 'submit[s]' the application and commits the act of infringement. In the case before us, there is no doubt that Apotex Canada is the principal party in interest and intends 'to engage in the commercial manufacture, use, or sale' of the drug, and thus is an applicant under the statute.'"). The more burdensome alter ego pleading standard upon which the district court relied has no place in the assessment of the viability of the patent infringement claim against Mylan N.V.

Finally, the district court erred in not accepting as true the allegations in the Complaint that each of the three Mylan defendants would benefit from the sale of

the Proposed Products upon approval of the ANDA. The district court reasoned that "[n]owhere in the Complaint does Celgene allege that Mylan[] N.V. prepared the ANDA, or will sell MPI's pomalidomide product upon its approval." Appx80. But that is contradicted by the allegations in the Complaint. Here, the Complaint clearly alleges that each of the Mylan defendants would "engage in the commercial manufacture, use, offer for sale, or importation into the United States of [Mylan's ANDA Products]," Appx121-122, that "Mylan will induce infringement of one or more claims of the … patent under 35 U.S.C. § 271(b) by making using, offering to sell, selling, and/or importing Mylan's ANDA products in the United States," Appx124, that "Mylan will intentionally encourage acts of direct infringement," Appx124, and that "Mylan will contributorily infringe one or more claims of the … patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Mylan's ANDA Products in the United States," Appx124. The Complaint not only defines "Mylan" to include all of the Mylan defendants, but also explains the basis for such definition—"Mylan Pharmaceuticals, Inc., Mylan Inc., and Mylan N.V. work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products." Appx120.

Such facts more than satisfy the plausibility standard. Celgene is not required to specify at the pleading stage the precise acts that Mylan N.V. undertook

with regard to the ANDA; rather, courts routinely hold more generalized allegations sufficient, particularly when the defendants are all members of the same corporate family. *See, e.g.*, *Cephalon, Inc. v. Watson Pharm.*, 629 F. Supp. 2d 338, 349 (D. Del. 2009) ("Parties 'actively involved' in preparing the ANDA are deemed to have 'submit[ted]' the ANDA, regardless of whether they are the named applicant; this is especially true where the parties involved are in the same corporate family.") (citation omitted); *see also Helsinn*, 2016 WL 1338601, at *8 n.6 (defendants "function together in the 'same corporate family,' as parent and subsidiary looking to distribute and market their generic . . . product"); *Warner Chilcott*, 2017 WL 603309, at *4 (recommending denial of motion to dismiss claims against Mylan Inc. and noting that a party submits an ANDA "if it participates in the preparation of the ANDA and intends to benefit directly from the ANDA by selling the ANDA product upon FDA approval"); *Endo Pharm. v. Actavis Inc.*, 2017 WL 522825, at *1 (D. Del. Feb. 8, 2017). In fact, courts not only have held such allegations sufficient generally, but have also done so specifically as to Mylan entities. *See Warner Chilcott*, 2017 WL 603309, at *4; *Allergan*, 2016 WL 1572193, at *5.

For all of these reasons, the district court erred in dismissing Mylan N.V. for failure to state a claim.

C. The District Court Abused Its Discretion In Denying Leave To Amend

At a minimum, the district court abused its discretion in declining to permit Celgene to amend its Complaint to add allegations against Mylan N.V. related to its role in preparing and submitting the ANDA filing, and how it will benefit from the ANDA, if approved.

"The court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2); *Mullin*, 875 F.3d at 149 (explaining "[t]his liberal amendment regime helps effectuate the general policy embodied in the Federal Rules favoring resolution of cases on their merits") (citation and quotation omitted). "A decision on whether to permit amendment of the pleadings generally falls within the District Court's discretion." *Id.* at 150. Leave to amend should be granted unless there is "substantial or undue prejudice, . . . bad faith or dilatory motives, truly undue or unexplained delay, repeated failures to cure the deficiency by amendments previously allowed, or futility of amendment." *Lorenz v. CSX Corp.*, 1 F.3d 1406, 1414 (3d Cir. 1993).

Here, the district court denied leave to amend because it concluded that the time for amendment had passed. Appx81. But that analysis—based on the scheduling order that applied to the Consolidated Actions—has no application in the instant case (even were it correct as to the Consolidated Actions). Celgene requested leave to amend in its opposition to Mylan's motion to dismiss in May

2020, and the operative scheduling order in the action on appeal (commenced in 2019) permitted amendment as of right until July 2020. *Celgene Corp. v. Hetero Labs Ltd., et al.*, No. 17-cv-3387, Doc. 717 (D.N.J. May 29, 2020); *see also* Appx1373. The district court therefore should have permitted leave to amend when it issued its opinion on September 2, 2020. *See Alvin v. Suzuki*, 227 F.3d 107, 122-23 (3d Cir. 2000) (reversing as an abuse of discretion denial of leave to amend based on case management considerations). Indeed, there had not been a prior amendment of the Complaint in this action, underscoring the impropriety of disallowing an amendment here. *United States ex rel. Customs Fraud Investigations, LLC. v. Victaulic Co.*, 839 F.3d 242, 250 (3d Cir. 2016) ("[W]e have rarely upheld a dismissal with prejudice of a complaint when the plaintiff has been given no opportunity to amend.").

Further, while courts may deny leave to amend when parties are put on notice of supposed defects in their pleading, nothing would have indicated to Celgene that its allegations as to Mylan N.V. were deficient (and, indeed, they were not) because the district court had *denied* the Mylan defendants' prior motion to dismiss. *Celgene Corp. v. Hetero Labs Ltd., et al.*, No. 17-cv-3387, Doc. 150 (Opinion) at 8 (D.N.J). And, as described *supra*, other courts have held patent infringement sufficiently pleaded against the family of Mylan entities based on

similar allegations. *See supra*, at 25.[4] The district court identified no "substantial or undue prejudice, . . . bad faith or dilatory motives, truly undue or unexplained delay, repeated failures to cure the deficiency by amendments previously allowed, or futility of amendment," *Lorenz*, 1 F.3d at 1414, and thus abused its discretion in denying Celgene leave to amend the Complaint to add allegations against Mylan N.V. related to its role in preparing and submitting the ANDA filing, and how it will benefit from the ANDA, if approved.

II. THE DISTRICT COURT ERRED IN DISMISSING MPI AND MYLAN INC. FOR IMPROPER VENUE

The district court also erred in concluding that the facts did not establish a *prima facie* showing of proper venue as to MPI and Mylan Inc.

A. Standard Of Review

"Whether venue is proper under § 1400(b) is an issue unique to patent law and is governed by Federal Circuit law." *In re ZTE (USA) Inc.*, 890 F.3d 1008, 1012 (Fed. Cir. 2018). This Court reviews "de novo the question of proper venue under 28 U.S.C. § 1400(b)." *Westech Aerosol Corp. v. 3M Co.*, 927 F.3d 1378, 1381 (Fed. Cir. 2019); *see also Valeant*, 978 F.3d at 1378. "[A]s a matter of

[4] The district court cited *Galderma Laboratories, L.P. v. Teva Pharm. USA, Inc.*, 290 F. Supp. 3d 599, 616 (N.D. Tex. 2017), to support dismissal of the Complaint against Mylan N.V., Appx58, but ignored that the court in *Galderma* not only recognized that other decisions "denied Rule 12(b)(6) motions on thinner allegations," but also granted leave to amend the complaint in that action. 290 F. Supp. 3d at 617, 619.

Federal Circuit law, upon motion by the Defendant challenging venue in a patent case, the Plaintiff bears the burden of establishing proper venue." *ZTE*, 890 F.3d at 1013. Where the district court "relies on pleadings and affidavits, the plaintiff need only make a *prima facie* showing of venue." 14D Charles Alan Wright & Arthur R. Miller, *Federal Practice & Procedure* § 3826 (4th ed. Oct. 2020). "Under that prima facie standard, the court must resolve all factual disputes in the plaintiff's favor." *Polar Electro Oy v. Suunto Oy*, 829 F.3d 1343, 1347-48 (Fed. Cir. 2016).[5]

Whether venue is proper under 28 U.S.C. § 1391 does not raise questions unique to patent law, and regional circuit law thus applies. *Cf. ZTE*, 890 F.3d at 1012. Under that general venue statute in the Third Circuit, the "defendant[s] ... bear the burden of showing improper venue." *Myers v. Am. Dental Ass'n*, 695 F.2d 716, 724–25 (3d Cir. 1982). Federal appellate courts generally review *de novo* the legal conclusion of whether venue is proper under 28 U.S.C. § 1391. *See Gulf Ins. Co. v. Glasbrenner*, 417 F.3d 353, 355 (2d Cir. 2005) (compiling cases).

[5] Although *Polar Electro* applies that *prima facie* standard in the context of a motion to dismiss for lack of personal jurisdiction, this Court treats venue and personal jurisdiction as "parallel cases" when formulating the burden and showing necessary to survive a motion to dismiss. *ZTE*, 890 F.3d at 1014 (holding plaintiff bears the burden of establishing proper venue, just as, "in the parallel case of personal jurisdiction, upon challenge by the defendant, plaintiff bears the burden of affirmatively establishing the first two elements of the due process requirement").

B. Venue For MPI And Mylan Inc. Is Proper In New Jersey Under The Patent Venue Statute

The totality of the evidence on the business MPI and Mylan Inc. conduct in New Jersey leads to the conclusion that each of MPI and Mylan Inc. has a "regular and established place of business" in the district. Each has geographic locations and regular agents in the district conducting the business of MPI and Mylan Inc., which satisfies Section 1400(b)'s "place of business" requirement. Those connections are strengthened further by business that Mylan affiliates conduct in the district, which may be imputed for venue purposes. And, under any conceivable legal standard for assessing where the patent infringement has occurred, venue is proper in New Jersey, where Mylan sent Celgene its Paragraph IV notice letters, asserting that Celgene's patents are invalid, and where Celgene will feel the brunt of the harm of the infringement if the ANDA is approved.

1. MPI And Mylan Inc. Have A Regular And Established Place Of Business In New Jersey

The inquiry for "regular and established place of business" is highly fact-specific—"no precise rule has been laid down and each case depends on its own facts." *In re Cray*, 871 F.3d 1355, 1362 (Fed. Cir. 2017). This Court has delineated "three general requirements relevant to the inquiry: (1) there must be a physical place in the district; (2) it must be a regular and established place of business; and (3) it must be the place of the defendant." *Id.* at 1362-63; *see also In*

re Cordis Corp., 769 F.2d 733, 737 (Fed. Cir. 1985) (noting that the appropriate inquiry is "not . . . whether it has a fixed physical presence in the sense of a formal office or store"). The regular and established place of business need not relate to the conduct at issue in the case. *See Bristol-Myers Squibb Co. v. Mylan Pharm. Inc.*, 2017 WL 3980155, at *21 (D. Del. Sept. 11, 2017) ("[N]o relationship between a defendant's acts of infringement and its regular and established place of business is necessary to satisfy § 1400(b)."); *Plexxikon Inc. v. Novartis Pharm. Corp.*, 2017 WL 6389674, at *2 (N.D. Cal. Dec. 7, 2017) ("The Court . . . concludes that the plain language of the statute does not include a nexus requirement."); *Genentech, Inc. v. Eli Lilly & Co.*, 2019 WL 4345788, at *3 (S.D. Cal. Sept. 12, 2019) (same).

(a) MPI And Mylan Inc. Have Physical Places Of Business In New Jersey

As to the first *Cray* factor, the requirement to establish the existence of a "physical place" in New Jersey is met through both the homes of MPI and Mylan Inc.'s employees and venue discovery in New Jersey.

To establish a physical place and therefore satisfy the first *Cray* factor, there must exist a "physical, geographical location[] in the district from which the business of the defendant is carried out." *In re Google LLC*, 949 F.3d 1338, 1343 (Fed. Cir. 2020) (holding presence of Google's servers in the district constituted a place under the first *Cray* factor). This Court has emphasized that any physical

location within the district satisfies the "place" requirement, such that a defendant need not possess "real property ownership or a leasehold interest in real property" because "a 'place' need not have such attributes." *Id.* Nor must the fixed physical presence be a "formal office or store." *Cordis*, 769 F.2d at 737. To the contrary, this Court has recognized that the physical locations that satisfy the "place" requirement include "leased shelf space or rack space," *In re Google*, 949 F.3d at 1343-44 (citing *Tinnus Enters., LLC v. Telebrands Corp.*, 2018 WL 4560742, at *4 (E.D. Tex. Mar. 9, 2018), *report and recommendation adopted*, 2018 WL 4524119 (E.D. Tex. May 1, 2018), and *Peerless Network, Inc. v. Blitz Telecom Consulting, LLC*, 2018 WL 1478047, at *3 (S.D.N.Y. Mar. 26, 2018)), and even "a table at a flea market," *id.* at 1343.

Here, the homes of the MPI and Mylan Inc. employees and the venue discovery venue discovery used for Mylan's products all satisfy the "place" requirement in New Jersey. As to the employees, the venue discovery MPI and Mylan Inc. employees' homes are geographical locations out of which MPI and Mylan Inc. work is conducted. In *Cordis*, this Court suggested that the homes of two of the defendant's sales representatives constituted a regular and established place of business because the employees conducted work out of home offices. 769 F.2d at 735, 737 (declining to issue writ of mandamus to reverse district court's denial of motion to dismiss for improper venue); *see also Cray*, 871 F.3d at 1364 n.1 (noting a defendant's

business model may ensure the "many employees' homes are used by the business as a place of business of the defendant"). The same is true here, as the MPI and Mylan Inc. employees worked out of the district for years before the complaint was filed, Appx2537, Appx2539-2542, Appx2544-2545, and, like the sales representatives in *Cordis*, provide New Jersey [redacted] and/or [redacted] for their work, Appx2681, Appx2683. Accordingly, these employees' home offices satisfy the first *Cray* requirement. *RegenLab USA LLC v. Estar Techs. Ltd.*, 335 F. Supp. 3d 526, 549 (S.D.N.Y. 2018) (holding "the 'physical place' requirement is satisfied through the home offices of certain Eclipse employees").

As to the [redacted], like the servers held to be physical "places" in *Google*, the [redacted] to [redacted] Mylan's products "are physically located in the district in a fixed, geographic location." 949 F.3d at 1343. These [redacted] contain Mylan [redacted] and are maintained and accessed by multiple MPI employees. Appx61. This Court has made clear that such locations used to [redacted] products constitute "physical, geographical location[s] in the district from which the business of the defendant is carried out." *Cray*, 871 F.3d at 1362 (citing *Cordis*, 769 F.2d at 735, for proposition that employees' homes are such "places" when used to store "literature, documents and products" and recognizing "distribution centers" and other locations that store "inventory" constitute

"places"). Accordingly, employees' homes and [venue discovery] in New Jersey qualify as a physical place and thus satisfy the first *Cray* factor.

(b) MPI And Mylan Inc.'s Places Of Business Are Regular And Established

As to the second *Cray* factor, the long-term nature of the MPI and Mylan Inc.'s employees' homes and the [venue discovery] maintained in New Jersey satisfy the requirement that the place of business be regular and established.

This Court has held that the "regular and established" factor "requires the regular, physical presence of an employee or other agent of the defendant conducting the defendant's business at the alleged 'place of business.'" *Google*, 949 F.3d at 1345. The requirement for "regular and established" will be met so long as the place of business is "steady, uniform, orderly, and methodical" and "settled certainly, or fixed permanently." *Cray*, 871 F.3d at 1362-63. The requirement for conducting business will be met where "the actual producing, storing, and furnishing to the customers of what the business offers" occurs. *Google*, 949 F.3d at 1346.

First, the MPI and Mylan Inc. employees regularly conduct business from their home offices. Some of the Mylan defendants' employees in the district worked for MPI or Mylan Inc. for years before the complaint in this action was filed. Appx2537, Appx2539-2542, Appx2544-2545. The extended and continuous presence of the Mylan defendants' employees in the district "demonstrates that the

business was established for purposes of venue." *Cray*, 871 F.3d at 1363 (referring to "a five-year continuous presence in the district"). And the MPI and Mylan Inc. employees provided New Jersey venue discovery and/or venue discovery for their work, including on venue discovery, Appx2681, Appx2683, indicating to potential and current customers that those employees could be contacted for work purposes at their New Jersey home offices and at venue discovery associated with New Jersey addresses. The district court discounted the New Jersey venue discovery on the Mylan venue discovery because "[n]othing in the record suggests MPI's business is actually carried out from the employee's home." Appx59. But the clear inference—which the district court should have drawn in Celgene's favor, *Polar Electro*, 829 F.3d at 1347-48—is that employees conduct business at the place where they advertise to customers that they can be found. Indeed, the district court concluded as much, stating that Celgene had demonstrated "that there exists within the district a physical location where an employee of the defendant carries on certain work for his employer." Appx59 (citing *Cray*, 871 F.3d at 1366).

The purposeful placement of employees in New Jersey also indicates the business is "regular and established." The Mylan defendants' venue discovery and venue discovery agents, including the venue discovery that MPI employs in New Jersey, work to "[a]chieve quarterly sales goals within the territory" and "[l]everage [Mylan's] sample program, literature and other items to ensure physician awareness of Mylan

Products." Appx2550-2551, Appx2553. Ultimately, venue discovery of venue discovery of dollars in sales of Mylan products are shipped to New Jersey each year. Appx2563, Appx2565, Appx2595, Appx2597. The district court wrongly deemed these sales "irrelevant" simply because they do not alone "establish a physical place in the district." Appx58 (quoting *Galdmera Labs, L.P. v. Teva Pharm. USA, Inc.*, 290 F. Supp. 3d 599, 613 (N.D. Tex. 2017)). But while sales may not establish a geographic location, they do indicate that regular and established business is conducted in the district. And here, as in *RegenLab*, 335 F. Supp. 3d at 550-51, sales "tasks necessitate proximity to customers," and demonstrate that sales agents "have not merely worked out of [the state in question] by happenstance." *See infra*, at 40.

Second, the venue discovery in the district, which are maintained by MPI's employees, constitute regular and established places of business. Indeed, the venue discovery are indistinguishable from warehouses as a physical location because the venue discovery are locations at which Mylan venue discovery are venue discovery so that the employees in the district have product on hand. And "[t]here is no question that warehouses are properly considered places of business and have been so held, by both legislatures and courts." *Seven Networks, LLC v. Google LLC*, 315 F. Supp. 3d 933, 958 n.35 & n.36 (E.D. Tex. 2018) (compiling legislative and judicial sources holding warehouses are places of business).

As with all business storage facilities, the Mylan defendants' venue discovery serve to maintain the Mylan venue discovery "in local districts to provide [defendants' customers] with quick access … avoiding delays associated with distant … retrieval" of the venue discovery. *Id.* at 960. Accordingly, that the Mylan defendant employees are not always present at the venue discovery does not preclude the finding that those venue discovery are regular and established places of business because the business conducted at those venue discovery (the venue discovery of venue discovery venue discovery) does not require the constant presence of Mylan personnel. *See Rensselaer Polytechnic Inst. v. Amazon.com, Inc.*, 2019 WL 3755446, at *12 (N.D.N.Y. Aug. 7, 2019) ("Thus, the relevant question is not whether Defendant's agents are present at all times at the Lockers but whether Defendant has agents conducting its business at the Lockers."). As part of their employment as sales and marketing employees, certain employees had access to and were required to access Mylan venue discovery in venue discovery in the district. Appx2537, Appx2667-2674, Appx2676-2679, Appx2719-2720. The venue discovery thus qualify as a regular and established place of business.[6]

[6] The district court indicated that Celgene did not "contend that the venue discovery themselves are regular and established places of business," Appx61, but in fact Celgene argued that the employees were required to conduct business at the venue discovery. *See Celgene Corp. v. Hetero Labs Ltd., et al.*, No. 17-cv-3387, Doc. 717 at 15 (D.N.J. May 29, 2020).

Finally, the fact that service of process could be effectuated on MPI and Mylan Inc. at their employees' homes in the district confirms that the "regular and established place of business" requirement of Section 1400(b) is met. In *In re Google*, 949 F.3d at 1344, this Court emphasized that, because the "regular and established place of business" language in the venue statute reflected similar language in the service statute, the finding that service could be effected on an agent's place of business in a district supports the finding that venue also lies in that district. Whether service can be effected by service on an agent generally turns on whether service was made "upon a representative so integrated with the organization that he [or she] will know what to do with the papers." *Direct Mail Specialists, Inc. v. Eclat Computerized Techs., Inc.*, 840 F.2d 685, 688 (9th Cir. 1988) ("Generally, service is sufficient when made upon an individual who stands in such a position as to render it fair, reasonable and just to imply the authority on his part to receive service."). Here, venue discovery of the Mylan Inc. employees working out of New Jersey includes a confidential venue discovery and venue discovery of venue discovery venue discovery and venue discovery. Appx2683. The Mylan defendants cannot credibly dispute that a confidential venue discovery "would know what to do" upon receipt of service papers.

(c) These Places Of Business Are Of The Defendants

The facts also demonstrate that MPI and Mylan Inc. have established or ratified a place of business in the district through their employees' residences, the marketing of its employees as operating out of New Jersey, and the use of venue discovery venue discovery as required locations for the distribution of Mylan venue discovery.

To show that the place of business is "'the place of defendant,'" "the defendant must establish or ratify the place of business." *Cray*, 871 F.3d at 1363. The factors relevant to ratification include not only whether the defendant owns or leases the place or exercises control over it, but also whether "the defendant conditioned employment on an employee's continued residence in the district or the storing of materials at a place in the district so they can be distributed or sold from that place." *Id.* Likewise, the court should consider representations to the public about the defendant's place of business, including any advertising or marketing that includes the address. *Id.* at 1363-64.

First, the employees' home offices are places of business of their Mylan defendant employers. As this Court explained in *Cray*, "[m]arketing or advertisements also may be relevant … to the extent they indicate that the defendant itself holds out a place of its business." *Id.* at 1363. Here, the employees' venue discovery clearly represent to potential customers those employees could be contacted at their New Jersey home offices and on venue discovery

venue discovery associated with New Jersey addresses, Appx2681, Appx2683. And those representations were connected to the Mylan defendants' employees' work: the venue discovery and venue discovery of Mylan products in the district require proximity to customers. *RegenLab*, 335 F. Supp. 3d at 550-51.

Indeed, when the Mylan defendants hire sales agents in specific locations, they often identify specific locations and require individuals to "live within [the] territory," Appx2553, or "live within [the] geography or within reasonable driving distance," Appx2547, Appx2551. These hiring requirements, too, "differentiate[] this matter from *In re Cray*, where 'no evidence showed that the defendant believed a location within the [district] to be important to the business performed,' or that the defendant had any intention to maintain some place of business in that district in the event the employees decided to terminate their residences as a place where they conducted business." *RegenLab*, 335 F. Supp. 3d at 552 (distinguishing *Cray*, 871 F.3d at 1365, on the basis that defendant "does solicit sales people in public advertisements to cover the [district] area and prefers that those employees live in their assigned sales area").

Second, the venue discovery of Mylan's products, which are necessary for the employees operating out of the district to be able to provide samples when marketing potential products, further evince the Mylan defendants' establishment and ratification of business in New Jersey. When elucidating the "of the

defendant" part of its tripartite analysis, *Cray* explained that "[a]nother consideration might be … the storing of materials at a place in the district so that they can be distributed or sold from that place." 871 F.3d at 1363. This consideration weighs in favor of treating the [redacted] as a place of business of the Mylan defendants, as those [redacted] facilitate the distribution of Mylan's [redacted] in the district. *See RegenLab*, 335 F. Supp. 3d at 552 (concluding the local inventory favors venue).

Third and finally, even if the employee residences and [redacted] were independently inadequate to establish venue, this Court generally assesses venue on a district-by-district rather than address-by-address basis. *See, e.g.*, *Cray*, 871 F.3d at 1362 (referring to "employees' homes" and "distribution centers," plural). Thus, even if the employees' homes do not alone qualify as the Mylan defendants' places of business, the combination of the physical [redacted] in the district and agents working in the same district together compels the conclusion that the Mylan defendants have a regular and established place of business in the district. As in *RegenLab*, 335 F. Supp. 3d at 552, the Mylan defendants' employees in New Jersey use the [redacted] to maintain Mylan [redacted], which are then used for sales. Taken together, the Mylan defendants' total involvement in the district more closely resembles that held sufficient to avoid a writ of mandamus by this Court in *Cordis*: the employees conduct the Mylan defendants' business out of

their residences while advertising as much, and maintain Mylan products in venue discovery venue discovery. 769 F.3d at 734.

The district court, however, suggested that if the products had been venue discovery in the employees' homes, the inference that the Mylan defendants had ratified the residences as places of business would have been strengthened. *See* Appx61 ("In fact, the use of separate venue discovery outside the employees' homes lends credence to the Court's conclusion that MPI has not ratified its employees' residences as its own place of business."). This analysis not only mistakenly evaluates each place of business independently, failing to consider the Mylan defendants' collective business locations and activities in the district, but also encourages putative defendants to escape venue merely by segregating work functions between different locations. This Court should not ratify such means of evading otherwise proper venue. *See Ithaca Ventures k.s. v. Nintendo of Am. Inc*., 2014 WL 4829027, at *7 (D. Del. Sept. 25, 2014) (There exists an "overriding public policy throughout the federal court system to discourage parties' attempts to circumvent the . . . venue laws.").

2. The Regular And Established Places Of Business Of MPI And Mylan Inc.'s Affiliates May Be Imputed To Them

The "regular and established place of business" inquiry also is satisfied here for MPI and Mylan Inc. based on their affiliates for which venue in the district is proper.

This Court and others have recognized that associated entities and employees are relevant to the analysis such that they can serve as the regular and established place of business of the defendant even absent a showing of alter ego. *See Minn. Mining & Mfg. Co. v. Eco Chem, Inc.*, 757 F.2d 1256, 1265 (Fed. Cir. 1985) ("*3M*") ("[V]enue . . . is proper with regard to one corporation by virtue of the acts of another, intimately connected, corporation.") (citing approvingly *Leach Co. v. General Sani-Can Manufacturing Co.*, 393 F.2d 183 (7th Cir. 1968)); *Javelin Pharm., Inc. v. Mylan Labs. Ltd.*, 2017 WL 5953296, at *3-4 (D. Del. Dec. 1, 2017) (reading *Cray* "as having provided further support" to the imputation theory adopted in *3M*, and explaining that a regular and established place of business can be created through other corporate entities having a regular and established pace of business); *Mallinckrodt IP v. B. Braun Med. Inc.*, 2017 WL 6383610, at *6 (D. Del. Dec. 14, 2017).

As relevant to the venue inquiry here, the regular and established place of business inquiry is met based on the places of business in New Jersey of Mylan affiliate MLI and imputed to MPI and Mylan Inc. through Mylan N.V.

As to MLI, this Court should consider MLI's regular and established place of business in the district as that of MPI and Mylan Inc. because the three entities were virtually indistinguishable for purposes of the instant patent infringement claim. MLI's ownership can be traced up to [redacted] venue discovery, which are wholly-

owned by venue discovery[7] MLI engaged in numerous activities on behalf of MPI and Mylan Inc. in relation to the ANDA filing, including venue discovery pomalidomide for use in the Proposed Products covered by the ANDA, and collaborating on analytical reports related to the pomalidomide used in products subject to the ANDA. *See, e.g.*, Appx2487-2488 (listing "confidential venue discovery" as the venue discovery); Appx2494-2496; Appx2499. MLI had only one venue discovery, who was also an venue discovery of Mylan Inc. *See* Appx2408; Appx2531-2532. And MLI portrayed itself as "doing business as" MPI in government records. *See, e.g.*, Appx2534. MLI had a physical location in South Orange, New Jersey through 2017. Appx2329. When MLI dissolved in late 2017, a venue discovery employee signed the lease termination and Mylan issued a notice that all correspondence should go to venue discovery Appx2410, Appx2517, Appx2528.

This overlap in the activities of MLI with MPI and Mylan Inc. supports a finding that MLI's business was "of the defendant[s]." *See, e.g.*, *Cray*, 871 F.3d at 1363-64 (explaining that similarity in activities between the defendant in its recognized places of business and activities in the alleged place of business may inform the "of the defendant" inquiry).

[7] Before its dissolution at the end of 2017, MLI was wholly-owned by venue discovery venue discovery, which is wholly-owned by confidential venue discovery, which is wholly-owned by venue discovery, which is wholly-owned by venue discovery, which is indirectly wholly-owned by venue discovery Appx2405-2406.

Indeed, the collective business of Mylan entities conducted at physical places in the district, ratified by Mylan N.V. (for which venue is indisputably proper under 28 U.S.C. § 1391(c)(3)) through its treatment of Mylan entities as one company, confirms venue is proper in the district. Mylan N.V. is a publicly-traded holding company that sits at the top of the Mylan family of companies. Appx326-327. Mylan has described itself as "One Mylan," with a "horizontally and vertically integrated platform with global scale," Appx327, and portrays itself as a "one-stop shop," Appx2687. When Mylan's New Jersey subsidiary Dey Pharma changed its name to "Mylan Specialty" in 2012, Mylan's CEO stated that "operating under one brand will allow us to speak with a more unified and powerful voice." Appx525.[8]

The interrelatedness of Mylan N.V.'s subsidiaries and affiliates (including MPI and Mylan Inc.) and their operations supports imputation of venue between Mylan entities. MPI and Mylan Inc. employees who reside in New Jersey all use one "@mylan.com" email domain address, showing that they are seamlessly part

[8] *See also* Appx529 (in portraying Mylan as a single entity: "[w]hen looking across our entire U.S. portfolio, one out of every 13 prescriptions filled – brand-name or generic – is a Mylan product"); Appx2690 (stating that Mylan, including all Mylan entities, has had "[m]ore generic drug applications approved by FDA over the last two years than any other company"); Appx531 (privacy statement explaining that "[t]he term '**Mylan**,' '**we**,' and '**us**' includes Mylan Inc. and our affiliates and subsidiaries") (emphasis original); Appx537 (CEO Heather Bresch characterizing all of the Mylan family, products, employees, and manufacturing sites as part of a single Mylan in her Congressional testimony).

of "One Mylan." *See, e.g.*, Appx2681, Appx2683. Likewise, Mylan uses one website in the United States—www.mylan.com—with one hiring webpage for all Mylan entities, *see* Appx541-542, one newsroom for press releases involving products from various subsidiaries, *see* Appx544, Appx547, and the same customer-service email address for products from supposedly different entities, *see* Appx549, Appx553 (use of customer.service@mylan.com for both Mylan Specialty and Mylan Institutional products). Mylan uses the same logo on its employees' [redacted] and for its products (and will use that same logo on its Proposed Products if its ANDA is approved). Appx689, Appx692 (collectively showing the same logo on the Mylan Specialty EpiPen® product and Mylan's Proposed Products). Employees of one Mylan entity report to employees of another Mylan entity. *See* Appx2700, Appx2705 (showing [redacted] employee [redacted] reporting to [redacted] employee [redacted]).[9]

Moreover, [redacted] attorneys typically review the ANDA Paragraph IV certifications, which [redacted] files. *See* Appx2383, Appx2386.[10] And Mylan entities have requested that government agencies treat their affiliates as one. Appx774. In

[9] In fact, one of Mylan Inc.'s employees who worked on Mylan's ANDA did not know which Mylan entity employed him. A2695 ("**Q**: [redacted] **A**: [redacted] **Q**: [redacted] **A**: [redacted].

[10] Mylan Inc.'s legal department "[redacted] to all [redacted] for [redacted]" Appx2389, and all [redacted] go to Mylan Inc., Appx2385.

petitions for *inter partes* review before the PTO, MPI has described Mylan Inc. and Mylan N.V. as the "real parties in interest." Appx2740. In other words, Mylan Inc. and Mylan N.V. are "clear beneficiar[ies]" that have "a preexisting, established relationship with the petitioner [MPI]." *Applications in Internet Time*, 897 F.3d at 1351.[11]

Additionally, Mylan submits letters to government agencies like the FDA that are sent by MPI, on behalf of Mylan Inc., and signed by an individual at Mylan N.V. *See, e.g.*, Appx721-726; *see also* Appx728-743 (sent on behalf of MPI from Mylan employees who "received or expect to receive payments from" Mylan Inc.); Appx745, Appx772 (citizen petition from Mylan Specialty signed by employee of Mylan Inc.). And Mylan N.V. treats its subsidiaries' products as its own. *See* Appx544, Appx546, Appx571 (testimony of Mylan N.V. witness stating that Mylan "sell[s] more than 635 products in the United States" and "has more than 200 ANDAs pending with FDA"). Mylan N.V. uses its subsidiaries to prepare and file its NDAs and ANDAs, including the ANDA that is the subject of this litigation. Appx118-120 (alleging MPI and Mylan Inc. prepare and/or aid in the preparation and submission of ANDAs); Appx120 (alleging that Mylan N.V.

[11] The ANDA here includes references to "venue discovery," confirming the corporate entities worked together on the ANDA—just as the Complaint alleges. *See* Appx1071 (providing "confidential intellectual property of venue discovery"); Appx1066 (venue discovery addressed to venue discovery); Appx1077 (naming "venue discovery" as "Name of venue discovery").

controls and directs the conduct of MPI and Mylan Inc.). And Mylan Inc. holds the intellectual property rights related to Mylan's logo and other Mylan subsidiaries' products. *See* Appx707; Appx718.

In sum, these facts demonstrate that the Mylan entities, including Mylan N.V., Mylan Inc., MPI, and MLI do not preserve the "formalities of corporate seperateness," *Javelin*, 2017 WL 5953296, at *4. The Mylan entities act as one entity, bolstering the conclusion that Mylan Inc. and MPI have a "regular and established place of business" in the district.

3. The Mylan Defendants Have Committed Acts Of Infringement In The District

The district court correctly held on Mylan's first motion to dismiss that each of the Mylan defendants had committed acts of infringement in the district. Appx42. This Court's recent decision in *Valeant* does not dictate a different result but instead confirms the district court's holding.

(a) The Mylan Defendants' Actions Related To Submission Of The ANDA Qualify As Acts Of Infringement In New Jersey

At the threshold, even under *Valeant*'s view that "acts of infringement" should be limited to those acts that are "sufficiently related to the ANDA submission," 978 F.3d at 1384, acts of infringement have occurred in New Jersey.

This Court recently held that venue under the second part of Section 1400(b) is proper only in those districts in which acts sufficiently related to the submission

of the ANDA occurred. *See Valeant*, 978 F.3d at 1384. An ANDA includes not only the original application but also "all amendments and supplements to the application." 21 C.F.R. § 314.3. In *Valeant*, this Court opted to "not define what all relevant acts involved in the preparation and submission of an ANDA might be, leaving those questions for other cases where the precise contours are presented and briefed." 978 F.3d at 1384 n.8.

At a minimum, the Paragraph IV notice and certification—by which an ANDA filer notifies patent holders that their patents are allegedly invalid or will not be infringed—must be included. As the Supreme Court has explained, the "highly artificial" act of infringement under 35 U.S.C. § 271(e)(2) occurs only when the ANDA filing contains a Paragraph IV certification. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) ("That is what is achieved by § 271(e)(2)—the creation of a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the *fourth type of certification* that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent." (emphasis added)). "An applicant who makes the fourth certification is required to give notice to the holder of the patent alleged to be invalid or not infringed, stating that an application has been filed seeking approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent, and setting

forth a detailed statement of the factual and legal basis for the applicant's opinion that the patent is not valid or will not be infringed." *Id.* at 677. Thus, to make a Paragraph IV certification, the applicant must provide the patent owner notice of the ANDA. 21 U.S.C. § 355(j)(2)(B)(iv)(II). As part of the Paragraph IV certification, the ANDA must include documentation that the Paragraph IV notice letter was received. 21 C.F.R. § 314.95(e). The governing regulations require supplementation of the ANDA with an amendment that contains a return receipt or a signature proof of delivery. *Id.*

The receipt of the Paragraph IV letter providing notice is not only a "relevant act" "sufficiently related to the ANDA submission," *Valeant*, 789 F.3d at 1384 & n.8, but also an essential part of the ANDA submission. The receipt by the patent holder of the Paragraph IV notice letter triggers the patent owner's infringement claim under § 271(e)(2). *Eli Lilly*, 496 U.S. at 677 ("Approval of an ANDA or paper NDA containing the fourth certification may become effective immediately only if the patent owner has not initiated a lawsuit for infringement *within 45 days of receiving notice of the certification*." (emphasis added)); *see also Eli Lilly & Co. v. Mylan Pharm., Inc.*, 96 F. Supp. 3d 824, 832 n.8 (S.D. Ind. 2015) ("[I]t is the act of filing the ANDA and sending the Paragraph IV notice . . . that creates harm by triggering a patent holder's forty-five days to initiate litigation.");

see also 21 C.F.R. § 314.107(b)(3)(i)(A) (30-month stay begins on the "the later of the date of receipt of the notice" letter by the patent owner).

Here, the Mylan defendants sent the required Paragraph IV notice to Celgene in New Jersey. Appx120. The Mylan defendants then, as part of the ANDA submission, were required to provide to the FDA documentation concerning the delivery of its notice letter to Celgene in New Jersey. 21 C.F.R. § 314.95. The mailing and receipt of the Paragraph IV notice letter, which must be filed as an amendment to the ANDA, is an act "sufficiently related to the ANDA submission." *Valeant*, 978 F.3d at 1384. Thus, under *Valeant*, the Mylan defendants "committed an act of infringement" in New Jersey through the Paragraph IV notice letter to Celgene in New Jersey.

(b) The Artificial Act Of Infringement Stemming From The ANDA Submission Extends Nationwide

In addition, because this Court repeatedly has indicated that the act of infringement committed in filing an ANDA is the manufacturing, marketing, and sales that will take place upon approval of the ANDA, this "artificial" infringement occurs wherever the product will be marketed and sold—generally, nationwide.

Under 35 U.S.C. § 271(e)(2), the act of infringement occurs "if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug … claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." As this Court

has held, this statutory language indicates the relevant infringement inquiry is "whether, if a particular drug sought to be marketed *were* put on the market, it *would* infringe the relevant patent." *Bristol-Myers Squibb Co. v. Royce Labs, Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995) (emphases in original); *see also Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997) ("[T]he statute requires an infringement inquiry focused on what is likely to be sold following FDA approval."). Thus, an ANDA filing constitutes no infringement at all "unless the ANDA seeks approval to manufacture, use, or sell the drug prior to expiration of a patent *that would otherwise be infringed* by such manufacture, use, or sale, *apart from* the provisions of § 271(e)(2)." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1356 (Fed. Cir. 2003) (emphases in original).

In this regard, the "highly artificial" part of the § 271(e)(2) act of infringement that the Supreme Court described, *Eli Lilly & Co.*, 496 U.S. at 678, is that "the allegedly infringing product has not yet been marketed," *Warner-Lambert*, 316 F.3d at 1355; *see also Eli Lilly & Co.*, 496 U.S. at 678 (noting that ANDA infringement claim concerns "whether commercial manufacture, use, or sale of the new drug (*none of which, of course, has actually occurred*) violates the relevant patent" (emphasis added)). "The act of infringement, which the Supreme Court has called 'highly artificial,' is nevertheless a defined and very real act of infringement that takes place *wherever the ANDA filer seeks to market its*

product." *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755, 772 n.2 (Fed. Cir. 2016) (O'Malley, J., concurring) (citation omitted) (emphasis added). Because nationwide approval is sought here (Appx118-120, Appx122), the artificial infringement occurs nationwide and submission of the ANDA constitutes an act of infringement in New Jersey. And, because the "act of infringement" for the ANDA filing extends nationwide, the second portion of Section 1400(b) is met for venue purposes in any district, including the District of New Jersey.

(c) The Effects Of The Mylan Defendants' Infringement Are Felt In New Jersey

Even were 35 U.S.C. § 271(e)(2) read more narrowly than the Supreme Court has read it, an "act of infringement has been committed" in New Jersey in this case because Section 1400(b), like other venue statutes for specific types of claims, gives rise to venue in the district in which the effects of the challenged action will be felt.

Under basic rules of statutory construction, statutes *in pari materia* or relating to the same subject matter should be interpreted in light of, and consistently with, one another. *See Wachovia Bank v. Schmidt*, 546 U.S. 303, 315-16 (2006) ("[U]nder the in *pari materia* canon, statutes addressing the same subject matter generally should be read 'as if they were one law.'") (citations omitted); *Cook v. Wikler*, 320 F.3d 431, 435 (3d Cir. 2003) (applying the *in pari materia*

canon).[12] This interpretive principle is especially applicable when the statutes adopt similar language about the same subject matter. *See, e.g.*, *Oscar Mayer & Co. v. Evans*, 441 U.S. 750, 755 (1979) (construing a provision of the ADEA that was "almost *in haec verba* with" a provision of Title VII to reflect judicial constructions of the Title VII provision); *Pichler v. UNITE*, 228 F.R.D. 230, 245 (E.D. Pa. 2005), *aff'd*, 542 F.3d 380 (3d Cir. 2008) ("[C]ourts should look to similarly phrased statutes to aid their interpretative labors.").

Section 1400(b), while related to venue for patent cases, is not the only venue statute that dictates venue will be proper where an act has been committed or has occurred. Both the venue statute for Federal Tort Claims Act actions and for claims under Title VII of the Civil Rights Act of 1964 are venue-specific statutes providing—like Section 1400(b)—that venue will lie in the district in which an act has been committed or occurred. 28 U.S.C. § 1402(b) (venue proper "only in the judicial district where the plaintiff resides or wherein the act or omission complained of occurred"); 42 U.S.C. § 2000e–5(f)(3) (venue proper in "any judicial district in the State in which the unlawful employment practice is alleged to have been committed . . ."). As a result, Section 1400(b) must be

[12] *See also* ANTONIN SCALIA & BRYAN A. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 252 (2012) (because statutes are part of the entire *corpus juris*, "laws dealing with the same subject . . . should if possible be interpreted harmoniously").

construed *in pari materia* with these statutes. *Lafferty v. St. Riel*, 495 F.3d 72, 82 n.12 (3d Cir. 2007) ("Although §§ 1404(a) and 1406(a) address different situations, *the doctrine of in pari materia nevertheless applies because both provisions deal with venue*.") (emphasis added); *cf. Wachovia*, 546 U.S. at 316 (holding canon did not apply to "venue and subject-matter jurisdiction" because "they are not concepts of the same order.").[13]

Both the Title VII venue statute and the Federal Tort Claims Act venue statute have been interpreted to include the judicial district where the effect of the harmful act is felt. *Reuber v. United States*, 750 F.2d 1039, 1047 (D.C. Cir. 1984), *abrogated on other grounds by Kauffman v. Anglo-Am. Sch. of Sofia*, 28 F.3d 1223 (D.C. Cir. 1994) (concluding venue proper under § 1402(b) in "the jurisdiction where its effects are directed"); *Passantino v. Johnson & Johnson Consumer Products, Inc.*, 212 F.3d 493, 506 (9th Cir. 2000) (For Title VII claim, "venue is proper in both the forum where the employment decision is made and the forum in which that decision is implemented or its effects are felt [by the plaintiff]."); *see also Tamashiro v. Harvey*, 487 F. Supp. 2d 1162, 1167 (D. Haw. 2006) (holding

[13] Courts do not require an absolute identity of subject matter for *in pari materia* to be a relevant and applicable canon of statutory construction. *See, e.g.*, *Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964) (patent law and antitrust law are *in pari materia*); *Am. Cyanamid Co. v. FTC*, 363 F.2d 757, 770 (6th Cir. 1966) ("The Federal Trade Commission Act may be construed *in pari materia* with the Sherman and Clayton Acts.").

venue proper in the District of Hawaii because effects of alleged failure to promote were encountered there); *Dean v. Handysoft Corp.*, 2005 WL 362662, *2 (E.D. Pa. Feb. 16, 2006) (determining venue proper in Pennsylvania where effects of employment decision were felt in Pennsylvania).

In construing the second part of Section 1400(b) *in pari materia* with these venue statutes, venue in the District of New Jersey is proper because the effects of Mylan's submission of its ANDA are felt in New Jersey. *Acorda*, 817 F.3d at 772 (O'Malley, J., concurring) ("[T]he targeted nature of an ANDA filing—which is intended to challenge a particular patent owned by a known party with a known location—makes the case at hand just like that in *Calder*—the harm is targeted only to these Delaware companies, occurs only in Delaware, and is only triggered by the filing of the ANDA."); Appx120. As a result, even if the artificial act of infringement associated with the ANDA submission technically occurs in one location, Mylan has committed an act of infringement in New Jersey for purposes of Section 1400(b) because the effects of it will be felt by Celgene, which is located in New Jersey.

C. Venue Over MPI And Mylan Inc. Is Proper In New Jersey Under The General Venue Statute

In the alternative, venue is proper over MPI and Mylan Inc. under 28 U.S.C. § 1391.

While the patent venue statute refers to its application in "[a]ny action for patent infringement," the scope of Section 1400(b) in reality is much narrower. For instance, it does not apply to actions against foreign entities, *see In re HTC Corp.*, 889 F.3d 1349, 1361 (Fed. Cir. 2018), and it does not apply to declaratory judgment actions for patent infringement, *see, e.g.*, *Jack Henry & Assocs., Inc. v. Plano Encryption Techs. LLC*, 910 F.3d 1199, 1203 (Fed. Cir. 2018), to which the general venue statute applies. While Section 1400(b) primarily targets past infringement, Hatch-Waxman cases are more analogous to declaratory judgment actions—they typically give rise to only certain types of forward-looking relief. *See Bristol-Myers Squibb*, 2017 WL 3980155, at *6 n.8 ("In some ways, the forward-looking nature of an infringement case under the Hatch-Waxman Act is similar to an action for a declaratory judgment of non-infringement or invalidity of a patent."); *Eli Lilly & Co. v. Eagle Pharm., Inc.*, 2018 WL 5314917, at *1 (D. Del. Oct. 26, 2018) (holding venue proper under 28 U.S.C. §§ 1391 and 1400(b) in Hatch-Waxman action).

Here, Celgene's patent infringement claims seek to prevent future infringement through the marketing and sale of a generic version of Pomalyst®. Appx128-129. Under the general venue statute, venue is proper for a corporation in any state "in which such defendant is subject to the court's personal jurisdiction with respect to the civil action in question." 28 U.S.C. § 1391(c)(2). Venue in the

district of New Jersey is thus proper as to both MPI and Mylan Inc. because both MPI and Mylan Inc. are subject to personal jurisdiction in this district by having prepared or facilitated the ANDA filing, the effect of which will be felt in New Jersey. *Acorda*, 817 F.3d at 760 ("Mylan's ANDA conduct is 'suit-related' and has a 'substantial connection' with Delaware because the ANDA filings are tightly tied, in purpose and planned effect, to the deliberate making of sales in Delaware (at least) and the suit is about whether that in-State activity will infringe valid patents.").

Indeed, applying the general venue statute here is particularly appropriate because it would further the policy goals of the Hatch-Waxman Act. While the Act gives patent holders to right to file the litigation and encourages efficient adjudication of ANDA disputes, the narrow application of Section 1400(b) often forces parallel litigation in different districts. *Cf. Valeant*, 978 F.3d at 1383, 1385. And, if in fact the artificial act of infringement for ANDA purposes does not extend nationwide, then applying the general venue statute to ANDA actions would prevent ANDA filers from funneling litigation into their preferred venues by selecting the point of ANDA submission. *See id.* at 1383. Accordingly, this Court should hold that Hatch-Waxman actions are governed by the general venue statute such that venue over MPI and Mylan Inc. is proper in the District of New Jersey.

CONCLUSION

This Court should reverse the district court's dismissal of Defendants Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan N.V.

Dated: January 19, 2021

Respectfully submitted,

/s/ *F. Dominic Cerrito*

F. Dominic Cerrito
Eric C. Stops
Ellyde R. Thompson
Frank C. Calvosa
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Ave., 22nd Floor
New York, NY 10010
(202) 849-7000
(202) 849-7100 (fax)
nickcerrito@quinnemanuel.com
ericstops@quinnemanuel.com
ellydethompson@quinnemanuel.com
frankcalvosa@quinnemanuel.com

Attorneys for Appellant Celgene Corporation

Jennifer L. Swize
JONES DAY
51 Louisiana Ave.
N.W. Washington, DC 20001
(202) 879-3939
jswize@jonesday.com

Matthew J. Hertko
JONES DAY
77 W Wacker Dr.
Chicago, IL 60601
(714) 557-7990
mhertko@jonesday.com

ADDENDUM TABLE OF CONTENTS

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, **Plaintiff,** **v.** **HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, HETERO DRUGS LIMITED, HETERO USA, INC., AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., AUROLIFE PHARMA LLC, EUGIA PHARMA SPECIALTIES LIMITED, APOTEX INC., APOTEX CORP., MYLAN PHARMACEUTICALS, INC., MYLAN INC., MYLAN, N.V., BRECKENRIDGE PHARMACEUTICAL, INC., and TEVA PHARMACEUTICALS USA, INC.,** **Defendants.**	**Civil Action No. 17-3387 (ES) (MAH)** **OPINION (FILED UNDER TEMPORARY SEAL)** [1]

I. INTRODUCTION

This matter comes before the Court by way of Defendants Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan, N.V.'s (the "Mylan Defendants") renewed Motion to Dismiss for Improper Venue and Failure to State a Claim. *See* Defs.' Mot. to Dismiss, Apr. 13, 2020, D.E. 687. The

[1] The Court has temporarily filed this Opinion under seal in an abundance of caution, because the parties filed much of the briefing and accompanying declarations and exhibits under seal. If the parties conclude that any part of this Opinion contains confidential information or highly sensitive material, they shall file a motion to seal under Local Civil Rule 5.3 by September 25, 2020.

Court has considered the parties' submissions, and held oral argument on August 26, 2020. For the reasons set forth below, the Court will grant the Mylan Defendants' motion.[2]

II. BACKGROUND

The instant litigation concerns various drug manufacturers' filings of Abbreviated New Drug Applications ("ANDA") to market generic versions of Plaintiff Celgene Corporation's ("Celgene") pomalidomide product, POMALYST®. *See* Compl. ¶ 1, May 11, 2017, D.E. 1. The patents-in-suit pertain to methods for treating multiple myeloma and pharmaceutical compositions containing pomalidomide. *See id.* ¶¶ 26-29, 31.

Celgene holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 355(a), for its pomalidomide product. *See id.* ¶ 30. The patents-in-suit are listed in the Food and Drug Administration's ("FDA") "Approved Drug Products with Therapeutic Equivalence Evaluations" publication. *Id.* ¶ 32. As part of the ANDA process, various generic manufacturers submitted written certifications to the FDA alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in their respective ANDAs ("Paragraph IV Certifications"). *See id.* ¶¶ 86-104; 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The generic manufacturers thereafter notified Celgene of those assertions, as well as their intentions to seek the FDA's approval to market their proposed products prior to the expiration of the patents-in-suit. *See* Compl. ¶¶ 86-104.

On May 11, 2017, Celgene filed patent-infringement actions against the Mylan Defendants and other manufacturers pertaining to United States Patents Nos. 8,198,262 ("'262 patent"); 8,673,939 ("'939 patent"); 8,735,428 ("'428 patent"); and 8,828,427 ("'427 patent"). *See* Compl.

[2] Pursuant to 28 U.S.C. § 636(c), the parties have consented to the Undersigned's jurisdiction to resolve this motion. *See* Notice, Consent & Reference of the Mylan Defs.' Renewed Mot. to Dismiss to a Magistrate Judge, May 14, 2020, D.E. 710.

¶¶ 86-285 (the "-3387 Consolidated Action"). As alleged in the Complaint, the Mylan Defendants' submission of an ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of 1 mg, 2 mg, 3 mg, and 4 mg pomalidomide capsules prior to the expiration of the patents-in-suit "constitutes infringement of one or more of the claims of [those] patent[s] under 35 U.S.C. § 271(e)(2)(A)." *Id.* ¶¶ 134, 179, 224, 269.

After the filing of those actions, the United States Patent and Trademark Office issued to Celgene United States Patent Nos. 9,993,467 ("'467 patent"); 10,093,647 ("'647 patent"); 10,093,648 ("'648 patent"); 10,093,649 ("'649 patent"); and 10,555,939 ("'5,939 patent"). This Court consolidated Celgene's suits pertaining to the '467 and '5,939 patents with the -3387 Consolidated Action. *See* Order, Apr. 27, 2020, D.E. 695; Order, Jan. 31, 2019, D.E. 294. Trial is scheduled to begin in the -3387 Consolidated Action on January 11, 2021. The civil action concerning the '647, '648, and '649 patents has a control trial date of April 15, 2021. *See generally Celgene Corp. v. Mylan Pharms. Inc.*, No. 19-5802 (D.N.J.) ("2019 Action").

1. The Mylan Defendants' First Motion to Dismiss

On August 9, 2017, the Mylan Defendants moved to dismiss the Complaint for improper venue pursuant to the Federal Rule of Civil Procedure 12(b)(3). *See* Mot. to Dismiss, Aug. 9, 2017, D.E. 56. The Mylan Defendants further asserted that the claims against Mylan Inc. and Mylan, N.V. must be dismissed pursuant to Rule 12(b)(6) based on their assertion that Mylan Pharmaceuticals Inc. ("MPI") was the sole entity who submitted the ANDA to the FDA. *See id.*

This Court denied the motion without prejudice. *See* Order, Mar. 2, 2018, D.E. 151. In an accompanying Opinion, the Court first held that "the Mylan Defendants do not 'reside' in New Jersey for purposes of" the patent venue statute, 28 U.S.C. § 1400(b). Op. at 4, Mar. 2, 2018, D.E. 150. Turning to the second half of the statute, the Court adopted the United States District Court

for the District of Delaware's interpretation of the phrase "where the defendant has committed acts of infringement." *Id.* at 4-6. Rather than encompassing just past acts, the Court held that "'acts of infringement' in the Hatch-Waxman context include acts 'the ANDA applicant non-speculatively intends to take if its ANDA receives final FDA approval, plus steps already taken by the applicant indicating its intent to market the ANDA product in this District.'" *Id.* (quoting *BristolMyers Squibb Co. v. Mylan Pharms. Inc.* ("*BMS*"), No. 17-379, 2017 WL 3980155, at *13 (D. Del. Sept. 11, 2017)). The Court was unpersuaded by the Mylan Defendants' attempt to distinguish *BMS*, and opined that "Mylan's argument would be stronger . . . if other district courts in this Circuit did not follow BMS after [*In re Cray*, 871 F.3d 1355 (Fed. Cir. 2017)] issued." *Id.* at 5-6. The Court thus held that the Mylan Defendants failed to meet their burden to show that they did not commit "acts of infringement" within this district. *Id.* at 6.

With respect to the "regular and established place of business" prong of 28 U.S.C. § 1400(b), the Court held that venue-related discovery was appropriate because the Mylan Defendants' motion predated the Federal Circuit's instructive opinion in *Cray*. *See id.* at 6-7. The Court ordered that the Mylan Defendants could renew their motion to dismiss following the conclusion of said discovery. *See* Order, D.E. 151.

2. Venue-Related Discovery

On April 10, 2018, the Court adopted as modified the parties' jointly proposed schedule for venue discovery. *See* Order, Apr. 10, 2018, D.E. 162. Delays quickly accrued, causing the parties to deviate from their proposed schedule. Following several modifications, the Court ordered, in relevant part, the parties to present any unresolved discovery disputes to the Court on or before October 18, 2018; and that venue-related discovery would close on the later of December

13, 2018, or forty-five days after the Court's resolution of any disputes. *See* Order, Sept. 10, 2018, D.E. 217. The Court further ordered that,

> [f]or purposes of this litigation only, if Mylan does not renew its Venue-Related Challenge within [fifty-nine] days of the completion of venue-related discovery, Mylan shall be deemed to have waived any defense or arguments under Fed. R. Civ. P. 12(b)(3) or Title 28, Chapter 87 of the United States Code.

Id. The parties had difficulties resolving their disputes prior to the October 18, 2018 deadline, which the Court subsequently extended to November 15, 2018. *See* Order, Nov. 5, 2018, D.E. 243; Defs.' Letter, Oct. 18, 2018, D.E. 235; Pl.'s Letter, Oct. 17, 2018, D.E. 233. On November 6, 2018, the parties presented myriad disputes for the Court's review. *See* Joint Letter, Nov. 6, 2018, D.E. 244.

By way of an Oral Opinion and Order dated January 30, 2019, the Court issued a decision on the parties' disputes. *See* Oral Op., Feb. 1, 2019, D.E. 298; Order, Jan. 30, 2019, D.E. 292. The Court emphasized that

> the parties' joint letter presents disputes pertaining to the majority of the discovery requests that Celgene has posed to the Mylan Defendants. This Court's ruling does not purport to resolve each and every dispute concerning each and every interrogatory and request for production. Instead, the Court's ruling is designed to rule on a number of the larger issues in order to afford the parties necessary guidance to resume their meet-and-confer on any remaining discovery disputes, and the Court expects that the parties, armed with its ruling today, will have the tools necessary to resolve among themselves any remaining issues.

Oral Op. at 3:1-12, D.E. 298.

On March 18, 2019, Celgene and the Mylan Defendants informed the Court that they were "continuing to meet and confer regarding their remaining venue-related discovery disputes and, as directed . . . , are using the Court's January 30 oral opinion as a guideline for resolving their disputes." Joint Letter, Mar. 18, 2019, D.E. 326. The parties further informed the Court that they

would "propose a schedule for the remaining venue discovery deadlines shortly." *Id.* No schedule was subsequently submitted for the Court's review.

On September 9, 2019, in light of the overwhelming number of merits-based discovery disputes that had arisen between Celgene and all of the defendants in the -3387 Consolidated Action, the Court appointed a Special Discovery Master for the purpose of making recommendations regarding any outstanding and forthcoming disputes. *See* Order, Sept. 9, 2019, D.E. 448. Celgene thereafter raised a number of venue-related disputes with the Special Discovery Master on October 28, 2019. *See* Pl.'s Letter, Oct. 28, 2019, D.E. 485. Celgene sought "materials (1) that the Court ordered Mylan to produce but that Mylan did not produce and (2) related to additional discovery disputes on which the parties attempted to follow the Court's guidance in the Transcript Opinion but subsequently reached impasse." *Id.* at 1-2. The Mylan Defendants objected to the production of additional documents, arguing, in short, that they had fully complied with the Court's prior ruling and that the additional discovery sought was irrelevant to venue. *See* Defs.' Letter, Nov. 8, 2019, D.E. 503.

On December 23, 2019, the Special Discovery Master granted in part and denied part Celgene's application to compel venue-related discovery. *See* Special Discovery Master Order No. 4, Dec. 23, 2019, D.E. 558. The Special Discovery Master ruled that

> the discovery ordered herein shall be produced within 21 days in order to provide Celgene with the information it needs to conduct a 30(b)(6) deposition on its alter-ego and other venue-related theories, if it so chooses. Any 30(b)(6) deposition on venue issues shall be noticed by Celgene within 10 days of receiving discovery from Mylan and shall be conducted within 20 days thereafter . . . .

Id. at 4-5. No objections were filed to the Special Discovery Master's Order.

3. The Mylan Defendants' Renewed Motion

On April 13, 2020, the Mylan Defendants renewed their motion to dismiss. *See* Mot., Apr. 13, 2020, D.E. 687. The parties have stipulated that resolution of this motion shall apply equally to the -3387 Consolidated Action, the 2019 Action, and the consolidated cases concerning the '467 and '5,939 patents. *See* Order, May 13, 2020, D.E. 706; Order, Apr. 5, 2019, D.E. 336; 2019 Action, Order, Apr. 22, 2019, D.E. 14. The Mylan Defendants seek dismissal for improper venue pursuant Rule 12(b)(3). They also seek the dismissal of the claims against Mylan Inc. and Mylan, N.V. for failure to state a claim upon which relief may be granted pursuant to Rule 12(b)(6).

III. MOTION TO DISMISS FOR IMPROPER VENUE

Proper venue in patent infringement cases against domestic corporations is governed by 28 U.S.C. § 1400(b). *See TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1518 (2017). The statute "is intended to be restrictive of venue in patent cases compared with the broad general venue provision." *In re ZTE (USA) Inc.*, 890 F.3d 1008, 1014 (Fed. Cir. 2018). When a case has been filed in the incorrect district, the district court "shall dismiss, or if it be in the interest of justice, transfer such case to any district or division in which it could have been brought." 28 U.S.C. § 1406(a). Celgene bears the burden of establishing that this district is the proper venue for these suits against the Mylan Defendants. *See ZTE*, 890 F.3d at 1013.

1. Forfeiture of the Venue Objection

Before the Court can reach the merits of the venue objection, the Court must first address Celgene's argument that the Mylan Defendants have forfeited their right to challenge venue at this late stage of the litigation. *See* Pl.'s Br. at 2-6, May 29, 2020, D.E. 717. Celgene contends that "Mylan has delayed and obstructed the Court-ordered discovery" throughout the approximately

two years that elapsed between the Court's decision on the original motion and the filing of the renewed motion. *Id.* at 3. According to Celgene,

> if Mylan had any interest in expediting its objection to venue in this District—as opposed to strategically waiting to file its motion until the eve of trial—it should have at least: (1) agreed to use the original discovery confidentiality order for venue-related discovery; (2) not repeatedly fought Celgene's discovery requests; and (3) quickly produced the requested discovery.

Id. at 5. Celgene also emphasizes that "Mylan has worked with a team of five other defendants . . . to develop litigation strategies," and has "collaborat[ed] with the joint defense group . . . to file three sets of joint invalidity contentions, file numerous joint motions to compel, conduct many joint depositions of Celgene's witnesses, and to file joint invalidity expert reports for all asserted patents." *Id.* Were litigation to begin anew elsewhere, Celgene continues, it would involve a significant duplication of effort and would pose the risk of inconsistent outcomes. *See id.* at 5-6. Based on the foregoing, Celgene submits that the motion should be denied. *Id.* at 6.

The Mylan Defendants, unsurprisingly, deny Celgene's accusations of delay. *See* Defs.' Reply Br. at 12-14, June 5, 2020, D.E. 721. They stress that venue discovery was mired with disputes given the overbreadth of Celgene's requests, that they have unambiguously challenged venue since the outset of this litigation, and that they have adhered to all Court orders regarding venue discovery. *See id.* Accordingly, the Mylan Defendants submit that this motion is ripe for a ruling on the merits. *Id.*

Incident to a district court's inherent authority to ensure the orderly and expeditious disposition of cases, the Federal Circuit has recognized circumstances beyond Rule 12 for a defendant's forfeiture of the right to challenge venue. *See In re Micron Tech., Inc.*, 875 F.3d 1091, 1100-01 (Fed. Cir. 2017) (citing *Dietz v. Bouldin, Inc.*, 136 S. Ct. 1885, 1891 (2016)). The Federal Circuit has explained "that discretion under '[t]his authority must be exercised with caution' to

avoid impairment of, among other things, the congressionally granted venue rights." *In re Oath Holdings Inc.*, 908 F.3d 1301, 1305 (Fed. Cir. 2018) (quoting *Micron*, 875 F.3d at 1101). And, of course, "[j]ust because a district court has the inherent power to [impose forfeiture] does not mean that it is appropriate to use that power in every case." *Columbia Sportswear N. Am., Inc. v. Seirus Innovative Accessories, Inc.*, 942 F.3d 1119, 1133 (Fed. Cir. 2019) (quoting *Dietz*, 136 S. Ct. at 1893).

Without seeking to set forth an exhaustive list of circumstances under which a party may forfeit a venue objection, the Federal Circuit has noted that "a scenario that presents at least an obvious starting point for a claim of forfeiture" involves "a defendant's tactical wait-and-see bypassing of an opportunity to declare a desire for a different forum, where the course of proceedings might well have been altered by such a declaration." *Micron*, 875 F.3d at 1102. The Federal Circuit also has observed that the objection's proximity to trial is a relevant consideration. *See Chamberlain Grp., Inc. v. Techtronic Indus. Co.*, 935 F.3d 1341, 1351 (Fed. Cir. 2019) ("Congress has provided express statutory confirmation of judicial authority to consider the timeliness and adequacy of a venue objection[.]" (quoting *Micron*, 875 F.3d at 1101)); *Micron*, 875 F.3d at 1102 n.4 (collecting cases wherein the Federal Circuit denied mandamus from the denial of a venue objection that was raised less than three months before trial); *see also* 28 U.S.C. § 1406(b) ("Nothing in this chapter shall impair the jurisdiction of a district court of any matter involving a party who does not interpose timely and sufficient objection to the venue."). The Federal Circuit also has suggested that judicial efficiency and other "interests of the judicial system and of other participants in the case" may factor into the forfeiture calculus. *Micron*, 875 F.3d at 1102; *see also Oath Holdings Inc.*, 908 F.3d at 1306 (noting that "respondents have not shown that the judicial interest in economy could support a determination of forfeiture of venue rights"

because "[t]he record simply does not indicate the type of significant judicial investment that might, in some circumstances, support a determination of forfeiture").

A finding of forfeiture is not warranted here. The parties have been litigating the issue of venue since the denial of the original motion to dismiss. The Court disregards the parties' finger-pointing on the question of who bears the blame for the delay associated with the Court-ordered venue discovery. The Court has not kept a proverbial scorecard tallying the parties' respective wins and losses regarding each dispute that arose. Nor does the Court intend to peek behind the curtain to ascertain whether either party failed to adequately meet and confer regarding their disputes throughout the discovery period. Suffice it to say that the Court endeavored, in the words of the Special Discovery Master, to grant Celgene's reasonable requests for discovery "without unduly burdening Mylan with unnecessary, overbroad discovery demands for materials not reasonably directed toward the theories of venue proffered by Celgene." *See* Special Discovery Master Order at 2, Dec. 23, 2019, D.E. 558. Moreover, forfeiture of a venue challenge is not intended to supplant existing remedies like Rule 37 for discovery violations, none of which was imposed here. Accordingly, this case does not involve the "tactical wait-and-see" approach that the *Micron* court disfavored.

As for the remaining considerations, the motion's proximity to trial is no longer an issue given that neither the -3387 Consolidated Action nor the 2019 Action is scheduled to proceed to trial this year. The Court also finds that the considerations of judicial economy and the expenditure of judicial resources weigh neutrally. The instant Hatch-Waxman case is not a simple infringement action by a patentee against a single putative infringer; rather, the -3387 Consolidated Action involves fourteen defendants who have largely coordinated their defenses to Celgene's infringement claims. Celgene and the other generic pharmaceutical manufacturers will proceed to

trial in this District irrespective of the outcome of this motion. The participation of a particular defendant group does not materially change the substantive issues that the Court must resolve after the conclusion of trial. Nor does the Mylan Defendants' continued participation in this action have any meaningful impact on the remaining pretrial proceedings or trial itself from a procedural perspective. In short, having completed the Court-ordered discovery, the Mylan Defendants are entitled to a ruling on whether venue is proper in this district.

2. Standard of Review

The Court must pause again to address certain preliminary issues before reaching the merits of the Mylan Defendants' motion; this time, the appropriate pleading standard and the burden of proof. Normally, the Court's starting place on a motion to dismiss for improper venue would be the allegations set forth in the Complaint. The general rule is that "[t]he Court will accept any venue-related allegations in the complaint as true, unless they are contradicted by the defendant's evidence." *Novartis Pharm. Corp. v. Accord Healthcare Inc.*, No. 18-1043, 2019 WL 2502535, at *2 (D. Del. June 17, 2019) (citing *Bockman v. First Am. Mktg. Corp.*, 459 F. App'x 157, 158 n.1 (3d Cir. 2012)).

There are no venue-specific allegations here, perhaps because the Complaint in the -3387 Consolidated Action predated *TC Heartland LLC*. There, the Supreme Court held that proper venue in a patent infringement action does not depend on whether the corporation is subject to personal jurisdiction in that particular judicial district. *See TC Heartland LLC*, 137 S. Ct. at 1517. Furthermore, before the Federal Circuit's decision in *ZTE*, whether Federal Circuit law governed the burden of proof was an unsettled question of law. Indeed, this Court initially held that regional circuit law applied, which would have obviated the need for Celgene to include venue-specific facts in its pleading. *See Great W. Mining & Mineral Co. v. ADR Options, Inc.*, 434 F. App'x 83,

86-87 (3d Cir. 2011) (stating that "it is not necessary for the plaintiff to include allegations in his complaint showing that venue is proper"); *Myers v. Am. Dental Ass'n*, 695 F.2d 716, 724-25 (3d Cir. 1982) (holding that the defendant bears the burden of proving the affirmative defense of improper venue when venue is laid pursuant to 28 U.S.C. § 1391). The Mylan Defendants' motion thus "raise[s] [several] interesting question[s] about the importance of a plaintiff's operative pleading in a patent venue determination analysis."[3] *Incipio, LLC v. Argento Sc By Sicura Inc.*, No. 17-1974, 2018 WL 4945002, at *2 (C.D. Cal. July 18, 2018).

Celgene's failure to adequately plead venue in the Complaint arguably dooms its opposition to the Mylan Defendants' motion. In *Westech Aerosol Corporation v. 3M Company, GTA-NHT, Inc.*, 927 F.3d 1378, 1381-82 (Fed Cir. 2019), the Federal Circuit affirmed the dismissal of a complaint based on the patentee's failure to plead any facts showing that the defendant had a regular and established place of business within the district. After the defendant moved to dismiss the complaint for improper venue, the patentee sought leave to amend its complaint to assert facts sufficient under 28 U.S.C. § 1400(b). *See id.*at 1380. The district court obliged the patentee's request, and denied the motion to dismiss without prejudice. *Id.* at 1381.

The patentee's amended pleading merely "parroted § 1400(b)." *Id.* at 1381. Consequently, the district court granted the defendant's renewed motion to dismiss. *Id.* The patentee appealed to the Federal Circuit, "fram[ing] its appeal as a question of the proper pleading standards for venue." *Id.* The Federal Circuit held that the patentee's conclusory venue allegations were insufficient to survive a motion to dismiss. *Id.* at 1382. The Federal Circuit first reiterated its prior

[3] None of the subsequent complaints against the Mylan Defendants contains any non-conclusory allegations regarding venue. *See Celgene Corp. v. Mylan Pharms. Inc.*, No. 20-2608, Compl. ¶ 28, Mar. 10, 2020, D.E. 1 ("Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b)."); 2019 Action, Compl. ¶ 29, Feb. 14, 2019, D.E. 1 (stating same).

holdings that "the plaintiff has the burden of establishing proper venue under 28 U.S.C. § 1400(b)," and that "venue under the patent statute is proper when the facts show that the defendant has a regular and established place of business physically located within the judicial district." *Id.* (citations omitted). In concluding that the amended complaint failed to meet those standards, the Federal Circuit emphasized that the patentee "failed to plead *any* facts showing [the defendant] had a regular and established place of business physically located in the [district]." *Id* (emphasis in original). The Federal Circuit explained:

> [The patentee], in effect, claims that in lieu of pleading facts, it is sufficient to parrot the language of § 1400(b). This is incorrect. Simply stating that [the defendant] has a regular and established place of business within the judicial district, without more, amounts to a mere legal conclusion that the court is not bound to accept as true. [The patentee's] recitation of § 1400(b) is insufficient to survive a motion to dismiss for improper venue.
>
> A presumption that facts pleaded in the complaint are true does not supplant a plaintiff's burden to plead specific facts showing that the defendant has a regular and established place of business physically located in the judicial district.

Id. (internal quotation marks omitted).

There are two key differences between *Westech Aerosol* and the case at hand. First, the instant motion to dismiss comes after the conclusion of venue-based discovery. Celgene has therefore presented this Court with *some* factual assertions regarding venue. The parties have submitted witness declarations, deposition excerpts, answers to interrogatories, document produced in discovery, and public documents in support of their respective positions. Courts routinely look to facts outside of the pleadings when adjudicating venue objections. *See Cray*, 871 F.3d at 1364 (evaluating the various venue facts submitted without discussing whether they had been plead in the operative complaint); *Bristol-Myers Squibb Co. v. Aurobindo Pharma USA Inc.* ("*BMS II*"), No. 17-374, 2018 WL 5109836, at *2 (D. Del. Oct. 18, 2018) (considering evidence

outside of the complaint on a renewed motion to dismiss pursuant to Rule 12(b)(3) following venue-based discovery).

Second, the patentee in *Westech Aerosol* expressly sought leave to amend its venue allegations. *See Westech Aerosol*, 927 F.3d at 1383 ("[The patentee] alleged no facts in its second amended complaint to show venue was proper in the Western District of Washington despite the district court's admonition that [the patentee] amend its complaint consistent with its Rule 11 obligations."). Celgene did not seek leave to amend the operative pleading to include factual allegations after the conclusion of the venue-based discovery. Nor did any party include a deadline to amend in their proposed discovery plan.

Had the parties not engaged in venue discovery, the Court would likely grant this motion without prejudice to Celgene's filing of an amended complaint that contains non-conclusory allegations concerning 28 U.S.C. § 1400(b)'s requirements. But since this Court has the benefit of a factual record, the Court will wade through the evidence to determine whether venue is proper.

Turning to those proofs, the applicable evidentiary showing on a motion to dismiss for improper venue appears to be an open question. *See Rensselaer Polytechnic Inst. v. Amazon.com, Inc.*, No. 18-549, 2019 WL 3755446, at *5 n.6 (N.D.N.Y. Aug. 7, 2019) ("There does not appear to be any Federal Circuit guidance on the requisite evidentiary showing for establishing § 1400(b) venue at the pleading stage . . . ."). Generally speaking, "[i]f the court relies on pleadings and affidavits, the plaintiff need only make a *prima facie* showing of venue." 14D Charles Alan Wright & Arthur R. Miller, *Federal Practice & Procedure* § 3826 (4th ed. Rev. 2018). "If the court holds an evidentiary hearing, however, the plaintiff must demonstrate venue by a preponderance of the evidence." *Id.* Based on the closely analogous situation of motion to dismiss pursuant to Rule 12(b)(2), the *prima facie* standard would also apply where (1) the parties engaged in venue-based

discovery, (2) the pertinent facts are in dispute, and (3) the substantive determination can be made without an evidentiary hearing. *See Polar Electro Oy v. Suunto Oy*, 829 F.3d 1343, 1347–48 (Fed. Cir. 2016) ("[A] plaintiff need only make a prima facie showing of personal jurisdiction where . . . the parties conducted jurisdictional discovery, the jurisdictional facts are in dispute, and the district court determined personal jurisdiction without an evidentiary hearing."); *Celgard, LLC v. SK Innovation Co.*, 792 F.3d 1373, 1376-77 (Fed. Cir. 2015) (holding that that prima facie standard, and not preponderance-of-the-evidence standard, applied for motion to dismiss for lack of personal jurisdiction following jurisdictional discovery where no evidentiary hearing was requested).

The parties have not requested an evidentiary hearing, and the Court concludes that such a hearing is unnecessary. *See Murphy v. Schneider Nat'l, Inc.*, 362 F.3d 1133, 1139 (9th Cir. 2004) ("Whether to hold a hearing on disputed facts and the scope and method of the hearing is within the sound discretion of the district court."). Although the crux of the parties' disagreement concerns the legal conclusions that flow from Celgene's proofs, the parties do dispute certain facts. *See, e.g.*, Pl.'s Br. at 16 (asserting that the Mylan Defendants' "facts concerning its employees show a one-sided, incomplete, and seemingly false picture"). As a result, Celgene must make only a *prima facie* showing of proper venue. "Under [the] prima facie standard, the court must resolve all factual disputes in the plaintiff's favor." *Polar Electro Oy*, 829 F.3d at 1347-48; *see also Charles Schwab Corp. v. Bank of Am. Corp.*, 883 F.3d 68, 81 (2d Cir. 2018) (stating that a prima facie "showing entails making legally sufficient allegations of jurisdiction, including an averment of facts that, if credited[,] would suffice to establish jurisdiction over the defendant" (alteration in original) (quoting *Penguin Grp. (USA) Inc. v. Am. Buddha*, 609 F.3d 30, 34–35 (2d Cir. 2010))).

3. Application of the Venue Statute

The patent venue statute provides that a civil action "may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business." 28 U.S.C. § 1400(b). A domestic corporation "resides" only in its state of incorporation—not any district in which the corporation is subject to personal jurisdiction, as is the case for the general venue statute. *See TC Heartland LLC*, 137 S. Ct. at 1517, 1520. It is undisputed that neither MPI nor Mylan Inc. resides in this district within the meaning of 28 U.S.C. § 1400(b).[4] *See* Op. at 4, D.E. 150; *see also* Compl. ¶¶ 20-22.

To establish that a defendant has a "regular and established place of business" under the second prong of the patent venue state, the plaintiff must show: "(1) there must be a physical place in the district; (2) it must be a regular and established place of business; and (3) it must be the place of the defendant." *Cray*, 871 F.3d at 1360 (holding that the home of an employee who worked remotely in the judicial district in which suit was filed was not a regular and established place of business of the defendant). Venue is improper if any of those three requirements are not satisfied. *See id.*

The patentee must first show "a physical, geographical location in the district from which the business of the defendant is carried out." *Id.* at 1362. That need not be a formal office space, but may be any physical place subject to a defendant's control. *See In re Google LLC*, 949 F.3d 1338, 1343 (Fed. Cir. 2020) (holding that "real property ownership or a leasehold interest in real property" are not necessary attributes of a "place" within the meaning of 28 U.S.C. § 1400(b)).

[4] 28 U.S.C. § 1400(b) does not govern venue as to foreign entities, such as Mylan N.V.; rather, they are subject to suit in any judicial district pursuant to 28 U.S.C. § 1391(c). *See In re HTC Corp.*, 889 F.3d 1349, 1356-57 (Fed. Cir. 2018). Accordingly, the Court's discussion of proper venue under 28 U.S.C. § 1400(b) is limited to MPI and Mylan Inc.

The "place" requirement can be satisfied where "a defendant use[s] its employees' homes to store its 'literature, documents and products'" or to "stor[e] inventory that the employees then directly [take] to clients." *Cray*, 871 F.3d at 1360 (quoting *In re Cordis Corp.*, 769 F.2d 733, 735 (Fed. Cir. 1985)). Similarly, "leased shelf space or rack space can serve as a 'place' under the statute . . . ." *Google*, 949 F.3d at 1343-44

Second, the place of business must be "regular"—in other words, "steady, uniform, orderly, and methodical"—as well as "established"—meaning "settled certainly, or fixed permanently." *Cray*, 871 F.3d at 1362–63 (alterations omitted). This *Cray* factor "requires the regular, physical presence of an employee or other agent of the defendant conducting the defendant's business at the alleged 'place of business.'" *Google*, 949 F.3d at 1345. A substantive analysis of the functions performed at the putative place of business must be undertaken. For example, there is a meaningful difference between an agent's maintenance of equipment and "the actual producing, storing, and furnishing to customers of what the business offers." *Id.* at 1346.

Finally, the "place" "must be a place *of the defendant* . . . ." *Cray*, 871 F.3d at 1363 (emphasis in original). Some form of ratification is required. *Id.* "Relevant considerations include whether the defendant owns or leases the place, or exercises other attributes of possession or control over the place." *Id.* Courts may also consider "whether the defendant conditioned employment on an employee's continued residence in the district or the storing of materials at a place in the district so that they can be distributed or sold from that place." *Id.* Another relevant consideration includes the defendant's representations to the public. *See id.* at 1363-64. That includes any advertising or marketing, use of the address in any physical or online directory, or the placement of the defendant's name on a sign associated with the building itself. *See id.* at

1364. Finally, courts may engage in a comparative analysis regarding the nature and activity of the business conducted across different venues. *See id.*

Neither Mylan Inc. nor MPI has a fixed, physical presence in New Jersey in the form of a company office or commercial space. Celgene thus relies on the presence of MPI and Mylan Inc. employees and affiliated entities in this district.

a. Employees of MPI & Mylan Inc.

Celgene submits MPI and Mylan Inc. have regular and established places of business in this district through the home offices of the [redacted] MPI and Mylan Inc. employees [redacted] *See* Pl.'s Br. at 14. Celgene points to the fact that "a number of these employees provide [redacted]" as evidence that these "employees took advantage of their ties to New Jersey for purposes of their jobs in this Judicial District." *Id.* Certain of these employees possess [redacted] *See, e.g.*, Decl. of Marta Godecki in Supp. of Celgene's Opp'n ("Godecki Decl."), Ex. 37, May 29, 2020, D.E. 717-2 ([redacted]). MPI and Mylan Inc. also sent non-resident employees to New Jersey to conduct business, as demonstrated by [redacted] during the relevant time period. *See* Godecki Decl., Exs. 33-34.

The [redacted] Mylan Inc. employees work in [redacted] Godecki Decl., Ex. 25. The [redacted] MPI employees include [redacted] *Id.* Certain of the MPI [redacted] employees have access to [redacted] *See* Godecki Decl., Exs. 35-36. As reflected in MPI's 2016 and 2017 [redacted]

[redacted]

[redacted] *See* Godecki Decl., Exs. 31, 32.

Based on several job postings, Celgene contends that these positions require living in the sales territory or within reasonable driving distance thereto. *See* Pl.'s Br. at 15. (citing Godecki Decl., Exs. 28-30). Celgene submits that MPI benefits from hiring its sales force for specific locations because, as the job postings state, these employees "work to '[a]chieve quarterly sales goals within the territory' and '[l]everage [Mylan's] sample program, literature and other items to ensure physician awareness of Mylan Products.'" *Id.* (quoting Godecki Decl., Ex. 29).

The foregoing proofs fall short of satisfying the *Cray* factors. In regard to the [redacted] Mylan Inc. employees, Celgene has not put forth any evidence suggesting that Mylan Inc. has held out those employees' homes as its place of business under the second and third *Cray* factors. The notation on a LinkedIn page that the Head of Global Risk is located in Basking Ridge, New Jersey, *see* Godecki Decl. Ex. 27, "indicates at most that [the employee] conducted business from the [District of New Jersey], not that [Mylan Inc.] established a place of business there," *Cray*, 871 F.3d at 1365. That is particularly true where, as here, the officer's LinkedIn page also suggests that her base or focus is the "Greater New York City Area." Godecki Decl. Ex. 27. Nor is there any evidence that Mylan Inc. played any role in the selection of the location of these employees' homes, or that Mylan Inc. "believed a location within the [District of New Jersey] to be important to the business performed . . . ." *Cray*, 871 F.3d at 1365. As the Mylan Defendants' affidavits bear out, [redacted] Supplemental Decl. of Keith Meckstroth in Supp. of the Mylan Defs.' Mot. to Dismiss ("Meckstroth Supplemental Decl.") ¶ 8, Apr. 13, 2020, D.E. 688-7.; *see also* Second Supplemental Decl. of Keith Meckstroth in Supp. of the Mylan Defs.' Mot. to

Dismiss ("Meckstroth 2nd Supplemental Decl.") ¶¶ 20, Apr. 13, 2020, D.E. 688-8 (attesting that [redacted]). Celgene has not put forth evidence to the contrary.

The evidence pertaining to MPI is a closer question, but ultimately does not carry the day. At the outset, evidence that the Mylan Defendants conduct business in New Jersey, in and of itself, is insufficient to establish a regular and established *place* of business within this State. The mere fact that revenue is generated from sales in this district is irrelevant. *See Galderma Labs., L.P. v. Teva Pharm. USA, Inc.*, 290 F. Supp. 3d 599, 613 (N.D. Tex. 2017) ("[T]he fact that [a defendant] may derive revenue from sales activities in the district does not establish a physical place in the district, as required by the patent venue statute."); *see also Symbology Innovations, LLC v. Lego Sys., Inc.*, 282 F. Supp. 3d 916, 931 (E.D. Va. 2017) ("Revenue derived from the forum has no bearing on whether § 1400(b)'s requirements are met."). Nor is the maintenance of a sales force akin to a regular and established place of business. *See Westech Aerosol Corp.*, 927 F.3d at 1381, 1382 n.1 (noting that the district court "agreed with [the defendant] that a sales presence in the judicial district did not, by itself, satisfy the patent venue statute"); *Warner-Lambert Co. v. C.B. Fleet Co.*, 583 F. Supp. 519, 523 (D.N.J. 1984) ("Where a defendant corporation merely employs sales representatives within a district without owning, leasing or controlling any real property located in the district, courts have declined to find a regular and established place of business."). The same is true with respect to the hotel stays by non-residents. Although hotel visits may serve a business purpose, those employees' presence in this judicial district in that manner is by definition "sporadic"—not "regular and established." *Cray*, 871 F.3d at 1362 (stating that "sporadic activity cannot create venue" and that a defendant's presence "must for a meaningful time period be stable, established").

Turning to the remaining factual averments and proofs submitted, which the Court views in a light most favorable to Celgene, the Court concludes that they do not establish a *prima facie* showing of proper venue as to MPI. There are no allegations or evidence that permit this Court to infer that MPI exercised any indicia of control over its employees' homes, or that MPI reimbursed any expenses related to their residences. What Celgene has proffered includes [redacted] and various job postings. *See* Godecki Decl. Exs. 28-30, 35-37. For the reasons set forth below, the Court cannot infer from these documents that MPI has ratified the various employees' residences in New Jersey; rather, these proofs "merely show that there exists within the district a physical location where an employee of the defendant carries on certain work for his employer." *Cray*, 871 F.3d at 1366.

The [redacted] would appear to help Celgene's cause. *See* Godecki Decl., Ex. 37. However, the Federal Circuit has cautioned that "the mere fact that a defendant has advertised that it has a place of business or has even set up an office is not sufficient; the defendant must actually engage in business from that location." *Cray*, 871 F.3d at 1364. Nothing in the record suggests MPI's business is actually carried out from this employee's home. In fact, [redacted] *See Regents of Univ. of Minn. v. Gilead Scis., Inc.*, 299 F. Supp. 3d 1034,1042 (D. Minn. 2017) (noting that "[w]hile the Court agrees that Gilead's employees service customers in Minnesota, whether through visits to healthcare providers or clinical trial facilities, this servicing occurs at the customer's physical place, not Gilead's"); *Precision Fabrics Grp., Inc.*

v. Tietex Int'l, Ltd., No. 13-645, 2017 WL 5176355, at *12 (M.D.N.C. Nov. 7, 2017) ("The listing of [an employee's] residential address and mobile telephone number on his business card indicates little beyond the fact [the employee] conducted business in the district."). Absent some suggestion to the contrary, this Court cannot conclude that the employees' physical residence mattered to MPI's business sufficient to constitute a regular and established place of business of MPI.

Celgene has also introduced an undated job posting for a sales position in New Jersey with an unspecified Mylan entity. *See* Godecki Decl., Ex. 29. Assuming *arguendo* that the position is representative of MPI sales positions during the relevant time period,[5] the Court nonetheless finds that the most salient takeaway from the job posting does not benefit Celgene. The posting states that the desired applicant "[m]ust live within geography of responsibility or *within reasonable driving distance*." *Id.* (emphasis added). As its plain language bears out, there is no requirement that the sales representatives actually live in New Jersey as a precondition for employment. A "reasonable driving distance" may cross state or district lines. The Federal Circuit has made clear that an employee's ability to move his or her home "out of the district at his or her own instigation, without the approval of the defendant . . . cut[s] against the employee's home being considered a place of business of the defendant." *Cray*, 871 F.3d at 1363. Celgene makes much of the point that [redacted]

[5] The Court disregards the two other job postings in the record. The first posting is for a Mylan Specialty L.P. sales position in Boise, Idaho, and is dated May 5, 2020. *See* Godecki Decl., Ex. 28. The other posting is for an account manager position with Mylan Institutional Inc. in the "Great Lakes" region, and is dated January 28, 2020. *See id.*, Ex. 30. Those postings provide no insight on the state of affairs in New Jersey in May 2017. *See Galderma Labs., L.P.*, 290 F. Supp. 3d at 612 ("The Court determines proper venue from the facts as they existed at time the Plaintiffs' Original Complaint was filed. . . . [E]vidence about a different entity's employment practices does not raise a fact issue as to whether [the defendant] employs sales representatives in the Northern District of Texas in 2017.").

[redacted] Pl.'s Br. at 16 (emphasis removed). For their part, the Mylan Defendants submit [redacted] Celgene has not refuted that assertion.

The final piece of evidence on which Celgene relies is MPI's [redacted] *See* Godecki Decl., Exs. 35-36. [redacted] do not belong to MPI. Rather, [redacted] Celgene does not contend that the [redacted] themselves are regular and established places of businesses. It appears that Celgene seeks to use the [redacted] as evidence to buttress the significant of MPI's presence in this District through its sales and marketing employees. *See* Pl.'s Br. at 15. That contention has no bearing on the crux of the Court's analysis. In fact, the use of [redacted] outside of the employees' homes lends credence to the Court's conclusion that MPI has not ratified its employees' residences as its own place of business.

The aforementioned proofs can be contrasted with those identified by the Federal Circuit in *Cordis*. There, the Federal Circuit held that the defendant's employees' homes, which were used to store the defendant's "literature, documents and products," could constitute a "regular and established place of business." *Cordis*, 769 F.2d at 737. The Federal Circuit rejected a mandamus request to reverse an order denying transfer for improper venue on the basis that the defendant used its employees' homes "like distribution centers, storing inventory that the employees then directly took to its clients." *Cray*, 871 F.3d at 1362 (citing *Cordis*, 769 F.2d at 735). Through two full-time sales representatives, the defendant sold cardiac pacemakers in the judicial district where it was sued. *See Cordis*, 769 F.3d at 735. The employees "complete[d] their paperwork and . . . other administrative tasks in their home offices," "[b]oth claim[ed] an income tax deduction for these offices," and utilized a secretarial service set up by their employer. *Id.* Both employees stored more than $30,000 worth of pacemakers in their homes. Clients, such as hospitals, could

obtain pacemakers directly from the employees' stock without a purchase order. *See id.* The employee would thereafter obtain payment for the device and replenish his or her home inventory by filing the necessary paperwork. *See id.* Here, unlike in *Cordis*, the MPI [redacted]

[redacted]

At bottom, the Court's conclusion does not turn on the resolution of disputed facts, but rather a dearth of facts that establish a *prima facie* case of proper venue through the presence of MPI and Mylan Inc. employees. This Court strained to credit the sparse, factual assertions contained in Celgene's opposition, and drew every favorable inference in Celgene's favor when it came to the exhibits. Based on this record, Celgene cannot impute the residences of MPI and Mylan Inc. employees to their respective employers for purposes of venue.[6]

b. Associated Entities

Celgene has put forth several theories to impute various related entities' presence to Mylan Inc. and MPI. Celgene submits that "associated entities . . . are relevant to the analysis such that they can serve as the regular and established place of business of the defendant; alter ego is not required." Pl.'s Br. at 10. Celgene alternatively advances an alter ego theory based on the Mylan Defendants' alleged disregard of corporate formalities. Celgene submits that "Mylan is effectively a single company, and Defendants, which are part of that tight-knit corporate family, operate as a unified front." *Id.* at 17. According to Celgene, "[a]s one entity, all of Mylan's presence in New Jersey is relevant, and further establishes that venue is proper as to MPI and Mylan Inc." *Id.* at 20. Celgene argues that any subsidiary's activities related to the ANDA must have been carried out for the benefit, and as an alter ego, of the Mylan Defendants. *See id.* at 13, 21. Specifically,

[6] It necessarily follows that Celgene would also fail the preponderance-of-the-evidence standard were that standard to apply.

Celgene submits that MPI and Mylan Inc. have a regular and established place of business in this district through non-party Mylan Laboratories Inc. ("MLI"). *See* Pl.'s Br. at 12-14, 21 (citing Godecki Decl., Exs. 12-24). Celgene further contends that venue is proper as to MPI and Mylan Inc. based on them being alter egos of MLI, Mylan, N.V., and non-party Agila Specialities Inc. ("Agila"). *See id.* at 21-23.

The Court first rejects Celgene's argument that venue may be imputed to the Mylan Defendants through associated entities without consideration of whether the Mylan Defendants abused the corporate form. With respect to MLI, Celgene does not articulate with any specificity the legal basis for imputing MLI's conduct to either MPI or Mylan Inc.—*i.e.*, based on principles of agency—but simply suggests that MLI's physical place of business is "of the defendant[s]" based on [redacted] *See id.*at 12-13.

The Federal Circuit has recognized that venue may be established pursuant to an alter ego or veil-piercing theory. *See Minn. Mining & Mfg. Co. v. Eco Chems., Inc.* ("*3M*"), 757 F.2d 1256, 1265 (Fed. Cir. 1985) (affirming the district court's ruling that venue was proper where individual shareholders "operated [the corporate defendant] without the oversight of a formal board of directors, without consulting the minority stockholders, and without adhering to the corporate formalities which normally serve to buttress the recognition of the corporation as a separate entity," and where the shareholders "purposely manipulated [the corporate defendant] so as to thwart [the plaintiff's] recovery of its judgment"); *see also Pearson v. Component Tech. Corp.*, 247 F.3d 471, 484 n.2 (3d Cir. 2001) (noting that "the tests employed to determine when circumstances justifying 'veil-piercing' exist are variously referred to as the 'alter ego,' 'instrumentality,' or 'identity' doctrines"; that "the formulations are generally similar"; and that "courts rarely distinguish them"). The Federal Circuit has not held that affiliation alone is sufficient, even if a parent company ratifies

the acts of a related subsidiary. To the contrary, the overwhelming majority of courts have required some proof of abuse of the corporate form in order to impute venue to a subsidiary.

The Court agrees with the majority view. "For purposes of venue, '[s]o long as a formal separation of [closely related] entities is preserved, the courts ordinarily will not treat the place of business of one corporation as the place of business of the other.'" *EMED Techs. Corp. v. Repro-Med Sys., Inc.*, No. 17-728, 2018 WL 2544564, at *2 (E.D. Tex. June 4, 2018) (alterations in original) (quoting 14D Charles A. Wright & Arthur R. Miller, Federal Practice and Procedure § 3823 (4th ed. 2018)); *see also Modern Font Applications LLC v. Peak Rest. Partners, LLC*, No. 19-221, 2020 WL 1692744, at *4 (D. Utah Apr. 7, 2020) ("As a general rule, a subsidiary's presence in a venue cannot be imputed to a parent unless the corporation disregards corporate formalities, lacks formal corporate separateness, or the subsidiary is the parent corporation's alter ego."); *Post Consumer Brands, LLC v. Gen. Mills, Inc.*, No. 17-2471, 2017 WL 4865936, at *3 (E.D. Mo. Oct. 27, 2017) ("[E]xcept where corporate formalities are ignored and an alter ego relationship exists, the presence of a corporate relative in the district does not establish venue."); *Galderma Labs., L.P.*, 290 F. Supp. 3d at 611 ("A subsidiary's presence in the district cannot be imputed to the parent for venue purposes so long as the two entities maintain formal corporate separateness. This is true even if the parent corporation controls the subsidiary's operations and the companies share a unitary business purpose." (internal citations omitted)); *Shapiro v. Ford Motor Co.*, 359 F. Supp. 350, 357 (D. Md. 1973) ("[E]ven where there is a unitary business purpose to manufacture and sell to ultimate consumers, if the operations of the two or more functional components of that unitary business purpose are themselves vested in formally separate entities, then venue over one under § 1400(b) cannot be gained by treating the regular and established place of business of the other as the office of the former.").

Celgene relies on a series of decisions from the United States District Court for the District of Delaware, wherein the court opined that "it follows from *Cray* that the 'place' of a corporate affiliate or subsidiary of a named defendant may, in at least some circumstances, . . . be treated as a 'place of the defendant.'" *Javelin Pharm., Inc. v. Mylan Labs. Ltd.*, No. 16-224, 2017 WL 5953296, at *4 (D. Del. Dec. 1, 2017); *see also Mallinckrodt IP v. B. Braun Med. Inc.*, No. 17-365, 2017 WL 6383610, at *4 (D. Del. Dec. 14, 2017); *UCB, Inc. v. Mylan Techs., Inc.*, No. 17-322, 2017 WL 5985559, at *4 (D. Del. Dec. 1, 2017). The court stated that, in contrast with the ratification of an employee's residence as a place of business, "it is likely more common for corporate parents to 'establish' or 'ratify' the place of business of their subsidiaries or other related corporate entities (with whom, for instance, they might share space)." *Mallinckrodt IP*, 2017 WL 6383610, at *4. The court acknowledged that *Cray* did not address this legal theory, but nonetheless concluded that it was not "frivolous," and therefore, sufficient to warrant venue-based discovery. *Id.* Critically, the court noted that "[a]mong the pertinent circumstances to be considered is whether the formalities of corporate separateness are preserved." *Id.*

This Court finds those cases to be inapposite. First, the Delaware court made the foregoing statements in the context of whether the patentee stated a non-frivolous basis to warrant venue-based discovery—not whether affiliation and ratification alone are sufficient on the substantive venue issue. Second, the Delaware court specifically acknowledged that a focal consideration is whether corporate formalities are observed—which is in accord with the Federal Circuit's decision in *3M*. And finally, notwithstanding the proposition that "[m]odern businesses are fluid, amorphous entities that operate on an interstate and international level," the Federal Circuit has repeatedly emphasized that the patent venue statute is construed narrowly. *In re BigCommerce, Inc.*, 890 F.3d 978, 985 (Fed. Cir. 2018) (internal quotation marks omitted); *see also Google*, 949

F.3d at 1346. Because venue is based on the *defendant*'s regular place of business, a subsidiary's presence in a judicial district should be imputed to the parent-defendant only when the subsidiary and parent are "alter egos" that operate without regard to their separate corporate identities.

Accordingly, the Court views Celgene's proofs through the lens of whether the Mylan Defendants disregarded the corporate form in their dealings with their respective subsidiaries and affiliates. If so, venue may be proper with respect to Mylan Inc. and MPI through the presence of associated entities in this district.

"Since the alter ego issue is not unique to patent law," regional circuit law governs. *Wechsler v. Macke Int'l Trade, Inc.*, 486 F.3d 1286, 1295 (Fed. Cir. 2007). Courts in this Circuit in turn apply state law. *See MSA Prod., Inc. v. Nifty Home Prod., Inc.*, 883 F. Supp. 2d 535, 540 (D.N.J. 2012) ("State law governs the Court's veil-piercing analysis.").

> Specifically, in New Jersey and most other jurisdictions, two elements must be shown to pierce the corporate veil: "First, there must be such unity of interest and ownership that the separate personalities of the corporation and the individual no longer exist. Second, the circumstances must indicate that adherence to the fiction of separate corporate existence would sanction a fraud or promote injustice."

Linus Holding Corp. v. Mark Line Indus., LLC, 376 F. Supp. 3d 417, 425 (D.N.J. 2019) (quoting *State Capital Title & Abstract Co. v. Pappas Bus. Servs., LLC*, 646 F. Supp. 2d 668, 679 (D.N.J. 2009)). When assessing whether there is a unity of interest among related entities, courts consider the following factors:

> [1] gross undercapitalization . . . ; [2] the failure to observe corporate formalities . . . , [3] the insolvency of the debtor corporation at the time, [4] siphoning of funds of the corporation by the dominant stockholder, [5] non-functioning of other officers or directors, absence of corporate records, and [6] the fact that the corporation is merely a facade for the operations of the dominant stockholder or stockholders.

Id. (citing *Craig v. Lake Asbestos of Quebec, Ltd.*, 843 F.2d 145, 150 (3d Cir. 1988)). The proofs related to the foregoing factors must evince "complete dominion"; "a parent's 'significant control' of its subsidiary is insufficient." *Las Vegas Sands Corp. v. Ace Gaming, LLC*, 713 F. Supp. 2d 427, 445 (D.N.J. 2010) (quoting *Craig*, 843 F.2d at 150). Stated differently, "a plaintiff must allege that the parent 'completely dominate[s] the finances, policy, and business practice with respect to the subject transaction' to such a degree that the subsidiary has 'no separate mind, will, or existence of its own.'" *Ramirez v. STI Prepaid LLC*, 644 F. Supp. 2d 496, 507 (D.N.J. 2009) (alteration in original) (quoting *Craig*, 843 F.2d at 150).

As for the second prong, "piercing the corporate veil is . . .an equitable remedy designed to remedy a fundamental unfairness perpetrated under the guise of the corporate form." *Linus Holding Corp.*, 376 F. Supp. 3d at 425. "Thus, in the absence of extraordinary circumstances, such as fraud or injustice, a court will generally decline to pierce the corporate veil." *Id.*; *see also Las Vegas Sands Corp.*, 713 F. Supp. 2d at 444 ("Even in the presence of corporate dominance, liability generally is imposed only when the parent has abused the privilege of incorporation by using the subsidiary to perpetrate a fraud or injustice, or otherwise to circumvent the law." (quoting *N.J. Dept. of Envtl. Prot. v. Ventron Corp.*, 468 A.2d 150, 164 (N.J. 1983)).

i. Mylan's Corporate Hierarchy

The Court begins with an overview of Mylan's corporate structure as set forth in the Complaint, Celgene's proofs, and the uncontested evidence proffered by the Mylan Defendants. Mylan, N.V. is a corporation organized and existing under the laws of the Netherlands. *See* Compl. ¶ 20; Meckstroth Supplemental Decl., ¶ 10. Mylan Inc. is a corporation organized and existing under the laws of Pennsylvania, having a principal place of business in Canonsburg, Pennsylvania. *See* Compl. ¶ 22; Meckstroth Supplemental Decl. ¶ 17. Mylan, N.V.'s executives carry out their

duties from Mylan Inc.'s Canonsburg location. *See* Compl. ¶¶ 20, 74. [redacted] Meckstroth Supplemental Decl. ¶ 3. MPI is a wholly owned subsidiary of Mylan Inc., which in turn is indirectly wholly owned by Mylan, N.V. *See* Compl. ¶¶ 23-24; Mylan Defs.' Second Supplemental Response to Interrogatory No. 8 ("2nd Supplemental Response to Rog. No. 8"), May 29, 2020, D.E. 717-2 at 45. [redacted] *See* Meckstroth 2nd Supplemental Decl. ¶¶ 7-11; Decl. of Keith Meckstroth in Supp. of the Mylan Defs.' Mot. to Dismiss ("Meckstroth Decl.") ¶¶ 5, 10-11, Apr. 13, 2020, D.E. 688-6. With respect to finances, [redacted] Meckstroth Supplemental Decl. ¶ 3.

Celgene seeks to establish proper venue through two non-party Mylan affiliates: MLI and Agila. MLI is a Delaware corporation that, before it dissolved in 2017, maintained an office in South Orange, New Jersey. *See* Meckstroth 2nd Supplemental Decl., Exs. A, C; 2nd Supplemental Response to Rog. No. 8, D.E. 717-2 at 45 (stating that MLI "filed a Certificate of Dissolution with an effective date of December 29, 2017"). MLI is [redacted] 2nd Supplemental Response to Rog. No. 8, D.E. 717-2 at 45. Agila is incorporated in the State of New Jersey, but does not own or lease any physical location in this State. *See* Meckstroth 2nd Supplemental Decl. ¶¶ 26, 28. Agila [redacted]

[redacted] 2nd Supplemental Response to Rog. No. 8, D.E. 717-2 at 45.

ii. Mylan Laboratories, Inc.

Celgene submits that [redacted] were carried out as an alter ego of the Mylan Defendants. Celgene further asserts that MLI's physical presence in the District of New Jersey before its dissolution satisfies the *Cray* factors.

Prior to its dissolution in 2017, MLI maintained a physical address in South Orange, New Jersey, *see* Meckstroch 2nd Supplemental Decl., Ex. C; possessed a wholesale license with the New Jersey Department of Health, *see* Godecki Decl., Ex. 12, D.E. 717-2 at 55; and [redacted] *see* Godecki Decl., Exs. 13-15. Celgene asserts that MLI's physical place of business satisfies the third *Cray* factor because [redacted] Pl.'s Br. at 12. Celgene emphasizes that [redacted] *see id.* (citing Godecki Decl., Ex. 16); that [redacted] *see id.* (citing Godecki Decl., Exs. 17-18); and that [redacted] that is the subject of this litigation, *see* Godecki Decl., Ex. 19.

In addition to the foregoing, Celgene submits that the Mylan Defendants disregarded the corporate form with respect to MLI. Celgene notes that the termination of MLI's lease in New Jersey was [redacted];

[redacted]; and that MLI has "portrayed itself as 'doing business' as Mylan Inc. in government records." *Id.* at 13 (citing Godecki Decl., Exs. 11, 21-23).

Celgene also relies heavily on the so-called "One Mylan" campaign as evidence that the Mylan Defendants are, in actuality, a single entity. Celgene points to examples of the Mylan Defendants' intermingling, including statements by Mylan's CEO referring to the various companies "operating under one brand"; employees' use of a "mylan.com" email address; a single "newsroom," hiring webpage, and customer-service email address across the companies; and the use of the same logo on products and business cards. *Id.* at 17-18 (citing Godecki Decl., Exs. 41-53). Celgene additionally notes that Mylan, N.V.'s executives operate out of the same location as Mylan Inc., that [redacted] *Id.* at 18. Mylan Inc. also owns intellectual property rights to the logo and various subsidiaries' products, while Mylan, N.V. holds out its subsidiaries' products as its own. *Id.* at 18-19 (citing Godecki Decl., Exs. 47-48, 59-60).

Celgene further emphasizes the Mylan Defendants' "unified front" when it comes various regulatory filings. *Id.* at 18-20. This evidence includes Mylan Inc.'s request to the FDA that its affiliated entities be grouped together for the assessment of a Generic Drug User Fee Amendments II Program Fee, MPI's representations in petitions for *inter partes* review that Mylan Inc. and Mylan, N.V. are the "real parties in interest," and the submission of letters to agencies wherein each Mylan Defendant is associated. *See* Godecki Decl., Exs. 54, 58, 61-62.

Even viewing the aforementioned proofs in the light most favorable to Celgene, the evidence does not support Celgene's argument that MLI is an alter ego of any of the Mylan Defendants. Celgene has put forth no evidence that another Mylan entity "completely dominate[d] the finances, policy and business practice" of MLI, *Ramirez*, 644 F. Supp. 2d at 507 (internal

quotation marks omitted), that MLI is undercapitalized or insolvent, that its officers and directors are strawmen, or that MLI lacks its own books and records.

The "One Mylan" campaign, as well as the Mylan Defendants' use of a single website, email address, and logo across all of their affiliates, does not demonstrate that corporate formalities have been ignored. "[T]he fact that the parent and subsidiary share the same 'brand' is insufficient." *Mills v. Ethicon, Inc.*, 406 F. Supp. 3d 363, 385 (D.N.J. 2019); *see also Laverty v. Cox Enters.*, No. 18-1323, 2019 WL 351905, at *4 (D.N.J. Jan. 29, 2019) (holding that subsidiary was not alter ego of subsidiary where plaintiff relied "on general corporate and marketing statements that vaguely touch on the relationship" between parent and subsidiary). "Accepting [Celgene's] position would extend the alter ego doctrine, such that entities utilizing the same brand, website, and policies would be imputed as alter egos." *Horowitz v. AT & T Inc.*, No. 17-4827, 2018 WL 1942525, at *9 (D.N.J. Apr. 25, 2018) (holding that "common marketing image and joint use of trademark logos" is insufficient to show alter ego).

The [redacted] is also insufficient to establish a corporate alter ego. *See United States v. Bestfoods*, 524 U.S. 51, 69 (1998) (stating that it is a "well established principle [of corporate law] that directors and officers holding positions with a parent and its subsidiary can and do 'change hats' to represent the two corporations separately, despite their common ownership"); *BMS II*, 2018 WL 5109836, at *4 ("[T]he fact that MPI and [its subsidiary] share one overlapping director does not demonstrate that corporate formalities have been ignored."). *Horowitz*, 2018 WL 1942525, at *8 ("A parent company's domination or control of its subsidiary cannot be established by overlapping boards of directors.").

Nor does [redacted] move the needle. There is nothing improper about [redacted]

[redacted] *See Pearson*, 247 F.3d at 485 ("[C]ourts have refused to pierce the veil even when subsidiary corporations use the trade name of the parent, accept administrative support from the parent, and have a significant economic relationship with the parent."). The record does not indicate that the [redacted] did not occur [redacted] or that [redacted]

Furthermore, multi-faceted entities within the same corporate family may share certain administrative functions, such as accounting, legal, and real estate, without forfeiting their formal legal separateness. *See Westfield Ins. Co. v. Interline Brands, Inc.*, No. 12-6775, 2013 WL 6816173, at *22 (D.N.J. Dec. 20, 2013) (declining to pierce the corporate veil where documentary evidence "suggest[ed] a parent-subsidiary relationship in which the lines between the distinct entities are occasionally blurred by the entities themselves or third parties" and noting that "cooperation between the entities for certain administrative functions, such as tax and payroll, is also insufficient"); *cf. Mark IV Transp. & Logistics v. Lightning Logistics, Inc.*, 705 F. App'x 103, 107 (3d Cir. 2017) (applying Tennessee law and concluding that "the sharing of resources and personnel," the use of the same attorneys, and the operation out of the same building "do not support piercing [the defendant's] corporate veil or the imposition of alter ego liability").

Based on the foregoing, Celgene has not demonstrated such domination of MLI by the Mylan Defendants that would warrant piercing the corporate veil and imputing MLI's physical presence in this district to either MPI or Mylan Inc. for venue purposes.

iii. Mylan, N.V.

Celgene seeks to shoehorn proper venue as to Mylan Inc. and MPI based on them being alter egos of their foreign parent, Mylan, N.V., which is not subject to 28 U.S.C. § 1400(b). *See HTC*, 889 F.3d at 1356-57. Celgene submits that MPI and Mylan Inc. are instrumentalities of

Mylan, N.V. as a result of their [redacted] disregard of the corporate form, and Mylan, N.V.'s claimed ownership of its subsidiaries' products as its own. Pl.'s Br. at 21. Celgene emphasizes that Mylan, N.V. is a publicly traded holding company [redacted] *See id.* Finally, Celgene surmises that Mylan Inc. [redacted]

Id. at 22.

For many of the same reasons set forth above, the Court is not persuaded that Celgene's proofs establish that MPI and Mylan Inc. are alter egos of Mylan, N.V. There is nothing inherently improper about Mylan, N.V.'s public-facing representations regarding "One Mylan" and its purported ownership of various subsidiaries' products. *See Horowitz*, 2018 WL 1942525, at *9 ("[A] company being 'portrayed as a single brand to the public . . . does not demonstrate the necessary control by defendant parent over the subsidiaries.'" (quoting *In re Enter. Rent–A–Car Wage & Hour Emp't Practices Litig.*, 735 F. Supp. 2d 277, 323 (W.D. Pa. 2010), *aff'd* 683 F.3d 462 (3d Cir. 2012)); *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 13 -2445, 2017 WL 4810801, at *11 (E.D. Pa. Oct. 25, 2017) ("[I]t is well recognized that a statement in an SEC filing in which a parent corporation is in some way consolidating by description its subsidiary's efforts and its own—for example, by stating that they are engaged in the "single business activity" of the manufacture and sale of [a drug product]—'is not atypical, and certainly does not suggest that, via fraud or its equivalent, the parent corporation has become indistinguishable from the subsidiary.'" (quoting *MacQueen v. Union Carbide Corp.*, No. 13-831, 2014 WL 6809811, at *7 (D. Del. Dec. 3, 2014)).

It is well-settled that Mylan, N.V.'s status as a holding company is not an abuse of the corporate form in and of itself. *See Horowitz*, 2018 WL 1942525, at *9 (stating that a "holding

company could simply hold another type of subsidiary" without demonstrating the indicia of an alter ego relationship (quoting *In re Enter. Rent–A–Car Wage & Hour Emp't Practices Litig.*, 735 F. Supp. 2d at 324)); *Transportation Ins. Co. v. Am. Harvest Baking Co., Inc.*, No. 15-663, 2015 WL 9049273, at *5 (D.N.J. Dec. 16, 2015) (concurring with the proposition that "in 'an ordinary holding company/subsidiary relationship, not one of undue domination and control,' there is no alter ego relationship" (quoting *Arch v. Am. Tobacco Co., Inc.*, 984 F. Supp. 830, 837-38 (E.D. Pa. 1997)).

Finally, although it is true that Mylan Inc. [redacted] the record does not indicate it is a sham corporation. [redacted] are not akin to gross undercapitalization. *See Las Vegas Sands Corp.*, 713 F.Supp.2d at 445 (stating that a corporation's "financial health in 2006 does little to answer the question of whether the corporation was established to defraud its creditors or [for] [an] other improper purpose"); *see also Laborers' Pension Fund v. Lay-Com, Inc.*, 580 F.3d 602, 612 (7th Cir. 2009) (explaining that undercapitalization is relevant for the purposes of veil-piercing because whether a corporation has adequate equity at the time of its formation factors into whether it is fair to disregard the limits on liability imposed as a result of the corporate form). [redacted] Celgene has provided this Court with no factual allegations or arguments from which this Court can discern foul play. It is not the Court's job to independently decipher and draw its own conclusions from exhibits without any direction from the party bearing the burden of proof. Accordingly, Celgene cannot impute the proper venue of Mylan, N.V. to either of its subsidiaries.

iv. Agila Specialties

Celgene's venue argument related to Agila turns on the first prong of 28 U.S.C. § 1400(b); that is, venue is proper as to Mylan Inc. and MPI because they are alter egos of Agila, which "resides" in this district within the meaning of *TC Heartland.* Celgene submits that MPI and Mylan Inc. are alter egos of Agila based on [redacted] For the reasons set forth above, the Court concludes that these assertions, without more, are insufficient to impute Agila's residence to MPI or Mylan Inc.

v. Veil-Piercing: Second Prong

Celgene also fails to establish "that adherence to the fiction of separate corporate existence would sanction a fraud or promote injustice." *Linus Holding Corp.*, 376 F. Supp. 3d at 425 (quoting *State Capital Title & Abstract Co.*, 646 F. Supp. 2d at 679). For its part, Celgene submits that "[f]ailure to find that Mylan Inc. or MPI are alter egos of MLI, Mylan, N.V. or Agila would frustrate the underpinnings of the Hatch-Waxman Act"; particularly, the Act's goal to "'facilitate[] the early resolution of patent disputes between generic and pioneering drug companies.'" Pl.'s Br. at 22 (quoting *Caraco Pharm. Labs. v. Forest Labs.*, 527 F.3d 1278, 1283 (Fed. Cir. 2008)). This Court fails to see how honoring the Mylan Defendants' corporate identities and requiring these patent suits to be litigated close to their state of incorporation or established place of business frustrates the Hatch-Waxman Act or, as Celgene also claims, is tantamount to sanctioning "forum shopping." *Id.*

The Federal Circuit has repeatedly emphasized that the very purpose of the patent venue statute is to avoid suits from taking place far away from the alleged infringer's place of business. *See Google*, 949 F.3d at 1346-47; *ZTE*, 890 F.3d at 1014; *Cray*, 871 F.3d at 1361. Nothing in the

record suggests that the Mylan Defendants, whose presence in New Jersey is limited, are seeking to circumvent that statute. Accordingly, Celgene has failed to carry its burden of proving an alter ego relationship among the Mylan Defendants and related entities.

* * *

Celgene has failed to establish a *prima facie* case of proper venue as to MPI and Mylan Inc. Neither entity has a regular and established place of business within this district.[7] The claims against Mylan Inc. and MPI shall be dismissed for improper venue pursuant to Rule 12(b)(3).[8]

IV. MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM AGAINST MYLAN, N.V. [9]

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Mammana v. Fed. Bureau of Prisons*, 934 F.3d 368, 372 (3d Cir. 2019) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). "A claim 'has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Sweda v. Univ. of Pa.*, 923 F.3d 320, 325 (3d Cir. 2019) (quoting *Thompson v. Real Estate Mortg. Network*, 748 F.3d 142, 147 (3d Cir. 2014)). The plausibility standard is not a "probability requirement"; the well-

[7] Having concluded that Celgene has not established Mylan Inc. and MPI have a regular and established place of business within this district, this Court need not address the parties' renewed arguments concerning the "acts of infringement" component of § 1400(b).

[8] At oral argument, Celgene stated it does not seek a transfer of this action in the event that the Court granted the Mylan Defendants' Rule 12(b)(3) motion, and that dismissal was appropriate remedy. In light of that representation, this Court exercises its discretion to order dismissal in lieu of transfer.

[9] The Mylan Defendants also seek dismissal of the claims against Mylan Inc. on Rule 12(b)(6) grounds. Because venue in this district is improper as to Mylan Inc., this Court declines to adjudicate that component of the Mylan Defendants' motion as a matter of comity. *See Alpine Bus. Grp., Inc. v. Sabathia*, No. 10-4850, 2011 WL 589959, at *2 (D.N.J. Feb. 10, 2011).

pleaded facts must do more than demonstrate that the conduct is "merely consistent" with liability so as to "permit the court to infer more than the mere possibility of misconduct." *Ashcroft v. Iqbal*, 556 U.S. 662, 678-80 (2009). The Court's analysis involves three steps:

> First, [the Court] will note the elements of a claim; second, [the Court] will identify allegations that are conclusory and therefore not assumed to be true, and; third, accepting the factual allegations as true, [the Court] will view them and reasonable inferences drawn from them in the light most favorable to [the non-movant] to decide whether they plausibly give rise to an entitlement to relief.

Sweda v. Univ. of Pa., 923 F.3d 320, 326 (3d Cir. 2019) (internal quotation marks and citations omitted). At the final step, the Court "must narrowly confine its inquiry to the allegations of the pleadings and their exhibits, matters of public record, and undisputedly authentic documents that form the basis of the claims." *EP Henry Corp. v. Cambridge Pavers, Inc.*, 383 F. Supp. 3d 343, 348 (D.N.J. 2019).

"The filing of an ANDA with a Paragraph IV certification constitutes an act of artificial patent infringement under 35 U.S.C. § 271(e)(2)(A) . . . ." *HZNP Medicines LLC v. Actavis Labs. UT, Inc.*, 940 F.3d 680, 684 (Fed. Cir. 2019). That provision prescribes that

> [i]t shall be an act of infringement to *submit* . . . an [ANDA] . . . for a drug claimed in a patent or the use of which is claimed in a patent,. . . . if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2)(A) (emphasis added).

"An entity submits an ANDA if it participates in the preparation of the ANDA and intends to benefit directly from the ANDA by selling the ANDA product upon approval." *Galderma Labs., L.P.*, 290 F. Supp. 3d at 615 (citing *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 528–29 (Fed. Cir. 2012)). The Mylan Defendants argue that Celgene fails to state a claim against

Mylan, N.V. because it was not the entity that submitted the ANDA at issue. Accordingly, "[t]he key inquiry for the Court is whether the [Complaint] sufficiently alleges that [Mylan, N.V. was] 'actively involved' in preparing the ANDA, as '[p]arties actively involved in preparing the ANDA are deemed to have submit[ted] the ANDA.'" *Galderma Labs, L.P.*, 290 F. Supp. 3d at 616 (third and fourth alterations in original) (quoting *Cephalon, Inc. v. Watson Pharm., Inc.*, 629 F.Supp.2d 338, 349 (D. Del. 2009)). "'Active involvement' includes 'marketing and distributing the approved generic drugs in the United States.'" *Id.* (quoting *Cephalon*, 629 F. Supp. 2d at 349).

As the parties point out, this Court is not the first to be faced with the argument that multiple entities in a corporate family "submitted" the ANDA. Although the cases are in accord on the overarching principles, the outcomes have not been uniform. That is not surprising because each decision turns, as it must, on the adequacy of the specific pleading at issue.[10] *Compare Galderma Labs., L.P.*, 290 F. Supp. 3d at 616–18 (granting motion to dismiss because the plaintiffs' "allegations do not distinguish [the parent company's] conduct from the [subsidiary ANDA filer's] conduct" and were not "supported by any specific factual assertions that make the allegation more than a bare-bones conclusion") *with Cephalon, Inc.*, 629 F.Supp.2d at 349 (denying motion to dismiss because the allegations the defendants "each took part in Generic Division operations and contributed employees to the various teams responsible for preparing the ANDA, and employees of each prepared and executed ANDA-related documents" were "sufficient to raise [the defendants'] active involvement in the preparation of the ANDA above the speculative level"). The allegations here are more analogous to *Galderma Laboratories, L.P.* than *Cephalon*.

[10] Accordingly, the Court is not bound by the two unpublished decisions from the United States District Court for the Eastern District of Texas, which held that the plaintiffs adequately stated a claim against Mylan Inc. *See Warner Chilcott Company, LLC v. Mylan Pharmaceuticals, Inc.*, No. 15-1471, 2017 WL 603309, at *4 (E.D. Tex. Jan. 19, 2017); *Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 15-1455, 2016 WL 1572193, at *5 (E.D. Tex. Apr. 19, 2016).

The Court must first discard the conclusory allegations that touch on this issue. *See Sweda*, 923 F.3d at 330. These statements include the allegations that "[MPI] acts at the direction, and for the benefit, of Mylan, N.V. and Mylan Inc., and is controlled and/or dominated by Mylan, N.V. and Mylan Inc.," Compl. ¶ 77; and Celgene's allegation that Mylan Inc. and MPI are "agents and/or alter egos" of Mylan, N.V., *id.* ¶ 72. "[A] plaintiff 'must plead specific facts with respect to how the affiliated entities and individuals allegedly controlled or dominated [the defendant]'" in order to rely on an alter ego theory. *High 5 Games, LLC v. Marks*, No. 13-7161, 2019 WL 3761114, at *6, 12 (D.N.J. Aug. 9, 2019) (quoting *Linus Holding Corp*, 376 F. Supp. 3d at 427). There are no such allegations here.

The conclusory allegations also include Celgene's contentions that the Mylan Defendants "work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products," Compl. ¶ 76, and that "following FDA approval of Mylan's ANDA, [the Mylan Defendants] will work in concert with one another to make, use, sell, or offer to sell Mylan's Proposed Products," *id.* ¶ 99. Crediting the unadorned supposition that the Mylan Defendants "work in concert" would result in a finding that Celgene stated a claim under 35 U.S.C. § 271(e)(2)(A) without any facts that suggest concerted action. Absent from the Complaint are any allegations that establish that Mylan, N.V. has any role in the day-to-day preparation of ANDAs or marketing and sale of pharmaceutical products—whether as a general matter or specific to the ANDA and proposed products at issue. The Court disregards those conclusory remarks.

Beyond recitations concerning the corporate hierarchy of the Mylan Defendants, *see* Compl. ¶¶ 20, 22-24, the remaining allegations are that (1) Mylan, N.V.'s executives "carry out the day-to-day conduct of Mylan, N.V.'s worldwide businesses at the company's principal offices

in Canonsburg, Pennsylvania," *id.* ¶ 20; (2) the Mylan Defendants collectively filed the ANDA at issue, *see id.* ¶ 98; Pl.'s Br. at 26 ("The Mylan defendants filed Mylan's ANDA."); and (3) the Mylan Defendants collectively provided the Paragraph IV Certification to the FDA and notice thereof to Celgene, *see* Compl. ¶¶ 100-01.

The Court takes issue with the latter two allegations. As the documents themselves bear out, [redacted] *See* Decl. of Sarah A. Siedlak in Supp. of Defs.' Mot., Ex. 4, Apr. 23, 2020, D.E. 688-4; Meckstroth 2nd Supplemental Decl., Ex. B, D.E. 688-8. Celgene's allegations that Mylan, N.V. submitted the relevant documents are therefore belied by the content of those documents. "When allegations contained in a complaint are contradicted by the document it cites, the document controls." *Jeffrey Rapaport M.D., P.A. v. Robin S. Weingast & Assocs., Inc.*, 859 F. Supp. 2d 706, 714 (D.N.J. 2012). Accordingly, the Court does not credit Celgene's allegations that Mylan, N.V. submitted the ANDA that serves as the basis for the infringement claims at issue.[11] Nowhere in the Complaint does Celgene allege that Mylan, N.V. prepared the ANDA, or will sell MPI's pomalidomide product upon its approval.

[11] The Court also notes that Celgene's reliance on group pleading is disfavored in this district. "Mere 'conclusory allegations against [d]efendants as a group' that 'fail[] to allege the personal involvement of any defendant' are insufficient to survive a motion to dismiss." *8 Erie St. JC LLC v. City of Jersey City*, No. 19-CV-9351, 2020 WL 2611540, at *3 (D.N.J. May 21, 2020) (quoting *Galicki v. New Jersey*, No. 14-169, 2015 WL 3970297, at *2 (D.N.J. June 29, 2015)). Facts must be alleged that establish each individual defendant's liability for the misconduct at issue. *See id.* "When a number of defendants are named in a complaint, a plaintiff cannot refer to all defendants 'who occupied different positions and presumably had distinct roles in the alleged misconduct' without specifying 'which defendants engaged in what wrongful conduct.'" *8 Erie St. JC LLC*, 2020 WL 2611540, at *3 (quoting *Falat v. County of Hunterdon*, No. 12-6804, 2013 WL 1163751, at *3 (D.N.J. Mar. 19, 2013)). Normally, the concern with group pleading concerns notice. *See Yu-Chin Chang v. Upright Fin. Corp.*, No. 19-18414, 2020 WL 473649, at *3 (D.N.J. Jan. 28, 2020). That issue is less prevalent when a plaintiff pleads wrongdoing against two entities in the same corporate family, as is the case here. Accordingly, Plaintiff's group pleading is not an independent basis for dismissal, but nonetheless is subject to scrutiny when reviewing the factual

In the absence of any non-conclusory allegations that establish Mylan, N.V.'s active involvement in the preparation of the ANDA and future marketing of the proposed products, Celgene has failed to state a claim for relief against Mylan, N.V. These claims are dismissed.[12]

V. CONCLUSION

For the reasons stated above, the Court grants the Mylan Defendants' Motion to Dismiss for Improper Venue and Failure to State a Claim. An Order consistent with this Opinion will issue.

s/ Michael A. Hammer
UNITED STATES MAGISTRATE JUDGE

Dated: September 2, 2020

allegations as a whole to determine whether Celgene has adequately pleaded a plausible basis for relief.

[12] Celgene argues in the alternative that the Court should grant it leave to amend the Complaint "to add additional allegations regarding the interconnectedness of Defendants, including with respect to their involvement in Mylan's ANDA." Pl.'s Br. at 28-29. Setting aside Celgene's failure to formally file a cross-motion, *see* Local Civ. R. 7.1(h), the deadline set in the Pretrial Scheduling Order to file any motion to amend has long since expired and Celgene has not offered any grounds that demonstrate good cause for modification of that deadline, *see Premier Comp Solutions, LLC v. UPMC*, -- F.3d --, 2020 WL 46682535, at *2 (3d Cir. Aug. 12, 2020) ("[W]hen a party moves to amend or add a party after the deadline in a district court's scheduling order has passed, the 'good cause' standard of Rule 16(b)(4) of the Federal Rules of Civil Procedure applies."). Indeed, Celgene has been on notice that the Mylan Defendants challenged the adequacy of the allegations against Mylan N.V. since August 2017, when the Mylan Defendants filed the original motion to dismiss. *See generally* Brief in Support of Mot. to Dismiss at 14, Aug. 9, 2017, D.E. 56-1.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, Plaintiff, v. MYLAN PHARMACEUTICALS INC., MYLAN INC., and MYLAN N.V., Defendants.	Civil Action No. 2:19-5802 (ES) (MAH) **ORDER OF DISMISSAL** *DOCUMENT FILED ELECTRONICALLY*

Pursuant to the April 22, 2019 Stipulation and Order (ECF No. 14) that the final resolution of Defendants Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan N.V.'s ("the Mylan Defendants") renewed Motion to Dismiss for Improper Venue and Failure to State a Claim (ECF No. 687 in Civil Action No. 2:17-3387 (ES) (MAH)), a copy of which is attached hereto as Exhibit A, shall equally apply to this matter, and the Court's subsequent September 2, 2020 Order (ECF No. 783) dismissing the Mylan Defendants in Civil Action No. 2:17-3387 (ES) (MAH), a copy of which is attached hereto as Exhibit B, it is hereby

ORDERED that Plaintiff Celgene Corporation's Complaint and claims against the Mylan Defendants and this action shall be, and hereby are, **DISMISSED**.

September 25, 2020
Date

s/Esther Salas
Hon. Esther Salas, U.S.D.J.

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, Plaintiff, v. MYLAN PHARMACEUTICALS INC., MYLAN INC., and MYLAN, N.V., Defendants.	C.A. NO.: 2:19-cv-05802-ES-MAH **STIPULATION AND ORDER**

Plaintiff Celgene Corporation ("Celgene") and Defendants Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan N.V. (collectively, "the Mylan Defendants"), by and through their undersigned counsel, hereby stipulate and agree as follows:

1. On May 11, 2017, Celgene filed a Complaint against the Mylan Defendants. ECF No. 1, Case No. 2:17-cv-03387-ES-MAH (the "First Case").

2. On August 9, 2017, the Mylan Defendants moved to dismiss the Complaint for improper venue, failure to state a claim, and lack of subject matter jurisdiction (the "Motion to Dismiss"). ECF No. 56, Case No. 2:17-cv-03387-ES-MAH.

3. On March 2, 2018, the Court issued an Order denying the Mylan Defendants' Motion to Dismiss without prejudice, permitting the parties to engage in venue-related discovery, and permitting the Mylan Defendants to renew their Motion to Dismiss following the conclusion of such venue-related discovery (the "March 2 Order"). ECF No. 151, Case No. 2:17-cv-03387-ES-MAH.

4. On February 14, 2019, Celgene filed a Complaint against the Mylan Defendants alleging infringement of U.S. Patent Nos. 10,093,647 (the "'647 patent"), 10,093,648 (the "'648

patent"), and 10,093,649 (the "'649 patent") (collectively, "the patents-in-suit"). ECF No. 1, Case No. 2:19-cv-05802-ES-MAH (the "Present Case").

5. The Mylan Defendants' Motion to Dismiss (ECF No. 56, Case No. 2:17-cv-03387-ES-MAH), including any new or renewed Motion to Dismiss filed in the First Case, and all papers submitted in support thereof or opposition thereto including requests for relief, legal arguments, and factual submissions included therein shall be incorporated herein and deemed to have and treated as having been filed in the Present Case, and shall apply equally to the Present Case and the Complaint herein, as if originally set forth and asserted herein.

6. The March 2 Order, a true and correct copy of which is attached hereto as Exhibit A, shall be deemed to have been and treated as having been filed in the Present Case and shall apply equally to the Present Case and the Complaint herein, as if originally set forth and asserted herein.

7. The Mylan Defendants shall not be required to file an additional Motion to Dismiss in the Present Case to preserve their challenges in this Case under Federal Rule of Civil Procedure 12(b)(3), 12(b)(1) and 12(b)(6) (as set forth in the Motion to Dismiss) (including but not limited to the filing of any appeal of the March 2 Order in the Present Case), and that such challenges shall not be waived or prejudiced by the Mylan Defendants' participation and/or their filing of any responsive pleading to the Complaint in the Present Case.

8. Celgene and the Mylan Defendants agree that final resolution of the Mylan Defendants' Motion to Dismiss (ECF No. 56, Case No. 2:17-cv-03387-ES-MAH), including any new or renewed Motion to Dismiss filed in the First Case, shall equally apply to the Present Case.

9. Any and all future filings and Orders of the Court concerning the Motion to Dismiss shall include the captions of and be filed in the First Case and the Present Case.

Dated: April 17, 2019

SAUL EWING ARNSTEIN & LEHR LLP

/s Charles M. Lizza
Charles M. Lizza
William C. Baton
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426
(973) 286-6700
Email: clizza@saul.com

Of Counsel:

F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Andrew S. Chalson
Gabriel P. Brier
Frank C. Calvosa
Marta A. Godecki
Brian J. Forsatz
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000

Anthony M. Insogna
Cary Miller, Ph.D.
JONES DAY
4655 Executive Drive, Suite 1500
San Diego, CA 92121
(858) 314-1200

Matthew J. Hertko
JONES DAY
77 W. Wacker Drive, Suite 3500
Chicago, IL 60601
(312) 782-3939

Attorneys for Plaintiff Celgene Corporation

Respectfully submitted,

SAIBER LLC

/s Arnold B. Calmann
Arnold B. Calmann (abc@saiber.com)
Jakob B. Halpern (jbh@saiber.com)
Monvan Hu (mhu@saiber.com)
One Gateway Center, 10th Floor, Suite 1000
Newark, New Jersey 07102
Telephone: (973) 622-3333

Of Counsel:

Elham Firouzi Steiner (esteiner@wsgr.com)
Nathaniel R. Scharn (nscharn@wsgr.com)
Sarah A. Siedlak (ssiedlak@wsgr.com)
WILSON SONSINI GOODRICH & ROSATI P.C.
12235 El Camino Real
San Diego, California 92130
Telephone: (858) 350-2300

Tung-On Kong (tkong@wsgr.com)
Wendy L. Devine (wdevine@wsgr.com)
Kristina M. Hanson (thanson@wsgr.com)
WILSON SONSINI GOODRICH & ROSATI P.C.
One Market Street
Spear Tower, Suite 3300
San Francisco, CA 94105
Telephone: (415) 947-2000

Attorneys for Defendants Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan N.V.

IT SO ORDERED this 22nd day of April, 2019.

HON. MICHAEL A. HAMMER
UNITED STATES MAGISTRATE JUDGE

EXHIBIT B

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, **Plaintiff,** **v.** **HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, HETERO DRUGS LIMITED, HETERO USA, INC., AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., AUROLIFE PHARMA LLC, EUGIA PHARMA SPECIALTIES LIMITED, APOTEX INC., APOTEX CORP., MYLAN PHARMACEUTICALS, INC., MYLAN INC., MYLAN, N.V., BRECKENRIDGE PHARMACEUTICAL, INC., and TEVA PHARMACEUTICALS USA, INC.,** **Defendants.**	**Civil Action No. 17-3387 (ES) (MAH)** **ORDER**

This matter having come before the Court by way of Defendants Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan, N.V.'s (the "Mylan Defendants") renewed Motion to Dismiss for Improper Venue and Failure to State a Claim [D.E. 687];

and the Court having considered the briefing and exhibits submitted in support of, and in opposition to, the motion;

and the Court having held oral argument on August 26, 2020;

and for the reasons set forth in an Opinion issued on this date;

and for good cause shown;

IT IS on this 2nd day of September 2020,

ORDERED that the Mylan Defendants' renewed Motion to Dismiss for Improper Venue and Failure to State a Claim [D.E. 687] is hereby **GRANTED**; and it is further

ORDERED that Celgene's claims against the Mylan Defendants be, and hereby are, **DISMISSED**.

s/Michael A. Hammer
UNITED STATES MAGISTRATE JUDGE

FORM 19. Certificate of Compliance with Type-Volume Limitations **Form 19**
July 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 2021-1154

Short Case Caption: Celgene Corporation v. Mylan Pharmaceuticals Inc.

Instructions: When computing a word, line, or page count, you may exclude any items listed as exempted under Fed. R. App. P. 5(c), Fed. R. App. P. 21(d), Fed. R. App. P. 27(d)(2), Fed. R. App. P. 32(f), or Fed. Cir. R. 32(b)(2).

The foregoing filing complies with the relevant type-volume limitation of the Federal Rules of Appellate Procedure and Federal Circuit Rules because it meets one of the following:

☑ the filing has been prepared using a proportionally-spaced typeface and includes 13929 words.

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☐ the filing contains _____ pages / _____ words / _____ lines of text, which does not exceed the maximum authorized by this court's order (ECF No. _____).

Date: 01/19/2021

Signature: /s/ F. Dominic Cerrito

Name: F. Dominic Cerrito

FORM 31. Certificate of Confidential Material **Form 31**
July 2020

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF CONFIDENTIAL MATERIAL

Case Number: 2021-1154

Short Case Caption: Celgene Corporation v. Mylan Pharmaceuticals Inc.

Instructions: When computing a confidential word count, Fed. Cir. R. 25.1(d)(1)(C) applies the following exclusions:

- Only count each unique word or number once (repeated uses of the same word do not count more than once).
- For a responsive filing, do not count words marked confidential for the first time in the preceding filing.

The limitations of Fed. Cir. R. 25.1(d)(1) do not apply to appendices; attachments; exhibits; and addenda. *See* Fed. Cir. R. 25.1(d)(1)(D).

The foregoing document contains 96 number of unique words (including numbers) marked confidential.

☐ This number does not exceed the maximum of 15 words permitted by Fed. Cir. R. 25.1(d)(1)(A).

☐ This number does not exceed the maximum of 50 words permitted by Fed. Cir. R. 25.1(d)(1)(B) for cases under 19 U.S.C. § 1516a or 28 U.S.C. § 1491(b).

☑ This number exceeds the maximum permitted by Federal Circuit Rule 25.1(d)(1), and the filing is accompanied by a motion to waive the confidentiality requirements.

Date: 01/19/2021

Signature: /s/ F. Dominic Cerrito

Name: F. Dominic Cerrito

FORM 30. Certificate of Service **Form 30**
July 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF SERVICE

Case Number 2021-1154

Short Case Caption Celgene Corporation v. Mylan Pharmaceuticals Inc.

NOTE: Proof of service is only required when the rules specify that service must be accomplished outside the court's electronic filing system. See Fed. R. App. P. 25(d); Fed. Cir. R. 25(e). Attach additional pages as needed.

I certify that I served a copy of the foregoing filing on 01/19/2021

by ☐ U.S. Mail ☐ Hand Delivery ☑ Email ☐ Facsimile
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on the below individuals at the following locations.

Person Served	Service Location (Address, Facsimile, Email)
Tung-On Kong	tkong@wsgr.com
Elham F. Steiner	esteiner@wsgr.com
Kristina M. Hanson	thanson@wsgr.com

☐ Additional pages attached.

Date: 01/19/2021

Signature: /s/ F. Dominic Cerrito

Name: F. Dominic Cerrito